AN *IN-VITRO* SEM STUDY COMPARING THE DEBRIDEMENT EFFICACY OF THE ENDOVAC® SYSTEM VERSUS THE CANAL CLEANMAX® FOLLOWING HAND-ROTARY INSTRUMENTATION

by

Benjamin P. Ricketts

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Joseph Legan

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B. Keith Moore

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Susan Zunt

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Mychel Vail
Chair of the Research Committee

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Kenneth Spolnik
Program Director

Date_____

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Behind virtually any personal achievement, there is a hidden support system consisting of family, friends, colleagues, and mentors who without credit, help facilitate the accomplishment. The conclusion of the following text will solidify my personal goal of a certificate in Endodontics with a master's degree in the Science of Dentistry and will represent the conclusion of my academic career at Indiana University School of Dentistry. Although I am overwhelmed with feelings of personal pride, it is glaringly obvious that the completion of these achievements and this chapter of my life are truly products of the help of many. In the absence of my support system, undoubtedly my accomplishments would have remained merely dreams, and these words would have never been created.

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INTRODUCTION

The main objective of endodontic therapy is to treat pulpal and periradicular tissues in order to retain the natural dentition so that normal form, function, and esthetics will be maintained.[1-3] From a physiology standpoint, root canal therapy is directed to prevent periradicular periodontitis.[1-5] Periradicular periodontitis is defined as inflammation, often with destruction, of periodontium that may or may not produce symptoms.[6, 7] In order for this inflammation to be of endodontic origin the pulp has had to have become either inflamed or infected to a point in which byproducts have permeated through the apex, lateral or accessory canals, or dentinal tubules to trigger an inflammatory vascular response in the periodontium.[8, 9] This response is primarily caused by pathogenic microorganisms such as bacteria, fungi, and viruses.[3, 9-17] Second, there are also non-living materials such as dentin and cementum chips as well as foreign debris that directly or indirectly illicit an inflammatory response.[1-3] Specifically, there are multiple studies illustrating a direct relationship between intracanal bacterial load and healing prognosis post-endodontic therapy.[9, 18-20] Thus, the main goal of all endodontic procedures is to remove canal contents, specifically living, infectious, microorganisms as well as necrotic and vital organic tissue.[1-5, 9, 21]

One of the key methods in removing canal contents is by cleaning and shaping, the root canal system.[1-3] This includes mechanically debriding the canal space, creating a reservoir to facilitate the delivery of disinfecting irrigation solutions and medicaments, and modifying the three dimensional anatomy to accommodate effective obturation[1-3, 22] Numerous manual and rotary instruments exist to facilitate cleaning and shaping of the

root canal system.[1-3] In order for these instruments to debride the canal, they must contact and plane the canal walls.[1-3] Although instrumentation is effective in removing the majority of canal contents, manual and rotary instruments are inefficient in completely debriding the canal.[23-26] This is due to the presence of multiple morphologic factors including lateral and accessory canals, canal curvatures, canal wall irregularities, fins, cul-de-sacs, isthmuses, and highly variable root anatomy. [3, 27-30]

Antimicrobial irrigation solutions are recommended as an adjunct to mechanical cleaning and shaping to eradicate microorganisms in a process known as chemomechanical debridement.[31] Chemical disinfection allows pathogens present in dentinal tubules, crevices, fins, isthmuses to be accessed, destroyed, and flushed from root canal system.[32, 33] Many irrigation solutions have been suggested for use during root canal therapy, such as sodium hypochlorite, chlorhexidine gluconate, and ethylenediaminetetraacetic acid (EDTA).[1-3] However, each solution in itself has limitations, and a combination of solutions is often used in an irrigation regimen to utilize the advantageous qualities of each irrigation solution separately.[34, 35]

Multiple studies have suggested that bacteria and debris remain within the root canal system, specifically in the apical one third, even after meticulous chemo-mechanical debridement.[30, 36-43] As previously discussed, a major reason for this ineffective disinfection is due to inadequate access of all aspects of canal walls to mechanical and chemical means. Improvement of mechanical access is limited by properties of the alloys within specific instruments and the immensely convoluted and variable root canal anatomy. However, multiple studies have suggested that the implementation of negative pressure irrigation and aspiration techniques can safely and

effectively increase efficacy of debris and smear layer removal from the walls of the root canal system.[44-46] The EndoVac (Discus Dental, Culver City, CA) and the Canal CleanMax (Maximum Dental, Inc., Secaucus, NJ) are irrigation systems that utilize negative pressure to irrigate and aspirate contents from the root canal system.

EndoVac consists of an irrigation syringe, or Master Delivery Tip, that connects to the high-vacuum suction of a standard dental unit. This tip limits delivery of irrigation solution to the coronal aspect of the access opening while simultaneously aspirating irrigating solution and debris. A MacroCannula or MicroCannula attached to the suction unit is utilized at different stages in the irrigation/aspiration process to pull irrigation solution deep into apical portions of canal while removing debris.[47-50] Many clinicians have shown concern with the seemingly complicated and time-consuming set-up of the EndoVac system, which may limit its use in clinical practice. Still others have reported instances in which the MacroCannula and/or MicroCannula become clogged during treatment, increasing time and cost for practitioner.

Canal CleanMax (Maximum Dental, Inc., Secaucus, NJ) is a new product that also implements negative pressure irrigation and aspiration via cannula-like "insert tubes." However, the system consists of a simple handpiece design which can be directly connected to a standard dental unit and provides both irrigation and aspiration in one device. The system also provides a button on the handpiece used to "flush" the system in the event that the "insert tubes" becomes clogged with debris.[51-54] To date, no published studies have evaluated the debridement or safety of the system.

The purpose of this investigation was compare root canal debridement efficacy of the EndoVac versus the Canal CleanMax following hand and rotary instrumentation.

REVIEW OF LITERATURE

HISTORY OF ENDODONTICS

The American Association of Endodontists defines endodontics as the branch of dentistry revolving around the morphology, physiology, and pathology of the human dental pulp and periapical tissues.[7] However, endodontics was once referred to as root canal therapy or pathodontia in the late nineteenth and early twentieth century.[55, 56] Despite the variation in nomenclature throughout history, the initial driving force of this specialty branch of dentistry was relief of odontogenic pain.

The "toothache" has seemingly plagued mankind since the dawn of time as evidenced by its description on Egyptian tablets, in Hebrew books, and from Chinese, Greek, and Roman medical writings.[56] One of the earliest descriptions of the toothache was credited to Fu Hsi in 2953 BC leading to the advent of various and often bizarre "cures" and "remedies."[57] These early therapeutic modalities involved the eradication or destruction of the "tooth worm," which seemingly provided the etiology for pain. The "tooth worm" theory originated in Babylonian times.[58] The Chinese described this mechanism via character inscriptions from the Ying Dynasty (1400 BC) depicting a worm on top of a tooth.[59] It was thought that the worm would inhabit the hollow portion of a tooth where it would gnaw at surrounding structure causing a toothache.[58] A recipe for a medicament for "curing the gnawing of the blood clot in the tooth," was described in the Ebers papyrus.[60]

Throughout the Middle Ages many "improved" methods of relieving odontogenic pain were recorded most of which still surrounded the popular belief that tooth decay and pain were caused by "worms."[56, 60] Andrew Boorde, a priest and physician in the late 15th century described a technique of "deworming" the tooth by letting the "perfume of the candle enter into the tooth and gape over a dish of cold water," at which point the worm could be removed and destroyed with he also described the alleviation of a toothache by cauterization of the nerve by "rendering it incapable of again feeling or causing pain."[61] This idea of cauterization was also supported by Peter Lowe in 1654.[57] Lazarre Rivierre recommended placing a cotton pellet moistened with clove oil into the tooth cavity for pain relief.[62] A similar solution of oil of cloves, eugenol, and zinc oxide is still used today but was not commercially available until its introduction by John Wessler in 1894.[63] Pierre Fauchard, the "founder of modern dentistry," would not publicly deny the existence of the "tooth worm." He indicated that these "worms" were not spontaneously generated but instead must have created a route into tooth structure from contaminated food, if in fact, they did exist.[58]

The "tooth worm" theory was largely debunked by the findings of Anton von Leeuwenhoek, who is regarded as the "father of modern microscopy." He identified worm-infested cheese, which he believed was the source of contamination.[64]

In 1728, Pierre Fauchard went on to criticize the early remedies for curing toothaches as he instead recommended rinsing the mouth with one's own urine every morning and night.[61] In his book entitled, *Le Chirurgien Dentiste ou Traite Des Dents* (*The Surgeon Dentist),* he also provided accurate descriptions of pulp cavities and root canals of various teeth.[56, 58, 61, 65] He described opening teeth and allowing them to drain

for a period of two to three months to relieve abscesses and evacuate pus. He would then use lead foil to fill the pulp chamber.[58, 61] Root canal therapy was not formally discussed, but Fauchard did describe a technique of pulp extirpation where a hole was drilled into the tooth by file or drill held in a brace. A roughened needle was used to remove the pulp and a cotton plug with oil of cloves or cinnamon was placed in the deep carious lesion. This plug could then be removed and replaced if pain persisted.[56, 58, 61]

A German by the name of L.B. Lenter recommended curing a toothache by means of electricity in 1756.[56, 66] In 1770, Thomas Berdmore addressed various causes and cures for the toothache including "obstructions and inflammation of the nerves." He recommended "counter-impression" or diverting the mind from the "disordered nerve," often by sedatives or burning of the ear with a hot iron.[56, 67] The first recorded description of an endodontic procedure in the US was credited to Robert Woofendale in 1776. He described a method of alleviating pain by cauterizing the pulp with a hot instrument and packing cotton into the open canals.[58, 61]

In 1802 B.T. Longbothom recommended that root canals be filled when it was inadvisable to extract them.[56, 58, 68] However, Edward Hudson most commonly receives credit for the first to fill root canals in 1809. He utilized his own instruments to pack gold foil in anterior teeth only.[56, 68, 69] In 1826, Leonard Koecker established criteria for capping of the exposed pulp, a procedure originally described by Pfaff.[56, 58, 70] In 1829, S.S. Fitch formulated and presented the doctrines of the "vitalistic" or "double membrane" theory in his book, *System of Dental Surgery*. He believed that teeth were like hollow bones with in an inner and outer periosteum that supplied roots with nourishment while the crown received its nourishment exclusively from the pulp or its

membrane. This theory suggested that only the crown would lose its vitality when the pulp was removed. [58, 71, 72] However, "non-vitalists" such as John Hunter, the eminent surgeon and scientist, believed that dentin had no circulation and did not possess any properties of a living tissue.[58, 72]

In 1836 Shearjashub Spooner introduced the usage of arsenic trioxide, a protoplasmic poison, to devitalize pulp tissue prior to its removal. The practice became immediately successful and popular as it was relatively painless. Although leakage of the solution through the root canal system would destroy adjacent vital supporting periodontal tissues, it was continually used until the 1920s.[58, 69, 73] In 1838 Edwin Maynard developed the first root canal broach by filing a watch spring.[58, 68, 74] In 1847 Edwin Truman introduced gutta-percha as a restorative and denture base material.[58, 75] Around1848 Hill[58, 73] combined gutta percha with quick lime, powdered glass, feldspar, and metal filings. The concoction was called "Hill's stopping" and was often used as a temporary restorative material.[58, 73] Throughout the 1850s, solution was often mixed with chloroform or eucalyptus oil and applied to plugs of wood soaked in creosote to fill root canals.[56, 58, 76] The rubber dam was originally created by S.C. Barnum in 1864 to isolate a tooth during gold foil operations and is the standard of care during endodontic therapy today.[56, 58, 68, 76] G.A. Bowman is credited as the first to have used gutta percha as the sole root canal filling material in 1867.[56, 58, 68] In the same year, Magitot recommended that pulp testing be performed with the use of an electric current, but its widespread use was not seen until it was suggested by J.S. Marshall 24 years later.[56, 58, 68] During this time period, pulp amputation was promoted to avoid necessity of instrumentation and filling of the root canal system. G.V. Black suggested the use of zinc oxychloride as a

pulp capping material in 1870, but its introduction was credited by N.C. Keep in 1876.[56, 58, 68, 69]

In 1878 G.O. Rogers suggested that pathogenic organisms were the most common etiology of the diseased pulp and that successful treatment would require their complete destruction. Thus, this conclusion helped put the theory of vitalism to rest and give rise to the septic theory. In 1882, under support of the new theory, Arthur Underwood hypothesized that disease would be prevented in the event that all pathogens were successfully excluded by the use of powerful and penetrating antiseptic agents. These caustic germicidal agents would be widely accepted for more than 30 years.[72, 77] A solution of chloroform and gutta percha, more commonly known as chloropercha, was introduced by Dr. Bowman in 1883.[56, 68, 77]

In 1884 Karl Koller suggested the use of cocaine as a topical anesthetic, which proved effective but toxic.[74] It was later used by E.C. Briggs to topically anesthetize the pulp.[68, 76] Procaine (Novocaine) was developed by Alfred Einhorn but not until 1905. It was first used for infiltration anesthesia prior to pulpal extirpation by H.S. Vaughn in 1906. Initially, a tablet was dissolved in solution, boiled, cooled, and aspirated into a syringe prior to mucosal injection. [56, 58, 69, 73, 74, 78]

In 1886 G.V. Black promoted amputation of individual severely periodontally compromised molar roots with root canal fillings used to preserve remaining roots.[79] As an avid supporter of the septic theory, W.D. Miller described the human mouth as a focus of infection. In 1888, he went on to depict the dental alveolar abscess as a continuation of pulpal infection. Miller indicated that any organ that is populated by bacteria and exhibits a point of decreased resistance can produce an abscess. His theories formulated

a bacteriological basis for endodontic treatment, which lead to recommendations of more time spent sterilizing carious dentin, sealing antiseptic in cavity preparations, and protecting it from saliva for a half hour.[77, 80, 81]

In 1895 William C. Roentgen discovered the x-ray, but the first dental radiograph was not acquired in America until later that year by a physician by the name of W.J. Morton.[77] C. Edmund Kells described the use of x-rays for diagnostic value as well as for the assessment of root canal obturation in 1899.[56, 77, 82] In 1908 Dr. Meyer Rhein formulated a technique to determine root canal length with a diagnostic wire in conjunction with dental radiographs, a system still utilized today.[68, 77] The first dental x-ray was available in 1913, but was not commercially available until 1919.[73]

Alfred Gysi introduced a cresol-Formalin mixture used for pulpal mummification in 1899 known as "triopaste," which contained paraformaldehyde as its main ingredient.[56, 77] Formocresol is a combination of tricresol and Formalin that first introduced by John Buckley in 1904 and still used in some dental applications today.[72, 77, 83, 84]

In 1901 T.W. Onderdonk recommended bacteriologic examination of the root canal system. His requirements prior to obturation included the absence of pain under temporary restoration and absence of bacteriologic culture after disinfection.[56, 68, 77, 78]

In 1909 E.C. Rosenow provided a study in which he showed that streptococci were present in many organs and readily capable of spreading infection to distant sites. This concept was further exploited by the English physician and pathologist William Hunter. This "focal infection" theory maintained widespread acceptance for the next 25 years and nearly killed American dentistry. [78, 85]

William Hunter provided a lecture, *The Role of Sepsis and Antisepsis in Medicine*, at McGill University in 1910 outlining the basis and concepts of the focal infection theory.[56, 85, 86] He attacked the antiseptic practices of the medical community: "Septic suppurations unfortunately occurred … as complications of various medical diseases." He ranked sepsis "the most prevalent and potent infective disease in the body." He applied these principles to the oral cavity but said the physician was immune to the possible disease processes occurring. He regarded oral sepsis as a "matter of teeth and dentistry." Statements referring to a gold crown as "a mausoleum of gold over a mass of sepsis" were intended to more acutely criticize the septic conditions surrounding inadequately fabricated prosthetic restoration. However, the widespread interpretation was applied to the pulpless tooth, condemned with a hopeless prognosis. Hunter's followers, known as the "one-hundred percenters" would extract all pulpless teeth in fear of focal infection. [85, 86] Specifically, they feared the possible systemic disease processes that Hunter attributed to oral sepsis, including gastritis, anemia, ulcers, colitis, and nephritis.[56, 86]

In 1912 M.L. Rhein attributed defective root canal treatment to the low fee schedule that forced dentists to use more efficient but less effective modalities.[85] He also used the volatile allegations of Hunter to help promote the enhancement of aseptic techniques utilized in dentistry, and specifically in the management of the pulpless tooth. He addressed Hunter's accusation of poor crown and bridge prostheses by stating, "If such be the facts, then let us acknowledge them honestly, and in attempting to drag ourselves from this quicksand of dishonor, let us not forget that instead of criticism we owe Dr. Hunter a debt of gratitude." In regards to root canal therapy, Rhein suggested

forgetting “antique methods of preserving dead pulp tissue,” and learning a scientific method of obtaining “strictly aseptic conditions."[56, 85, 87] These statements were the driving force in his attempts to adopt better root canal procedures focusing on enhanced asepsis via use of rubber dam and implementation of adequate access preparations.

W.H.G. Logan also responded to the focal infection theory and the widespread idea of oral sepsis in 1913 by demonstrating the successful treatment of chronic dentoalveolar abscesses without extraction to prevent the spread of sepsis.[56, 88] He later showed in 1937 that the presence of bacteria did not automatically signify the presence of infection.[85]

E.C. Rosenow and F. Billings continued to expand upon the idea of focal infection and elective localization. It was their belief that bacteria possessed a predisposition to inhabit specific distant areas of the body from original site of infection. Rosenow supported this conclusion by isolating *Streptococcus viridians* from tubes of media surrounding extracted teeth. [56, 89-93]

A turning point in dental research occurred in 1917, when more emphasis was placed on biologic principles of root canal therapy.[94] F.K. Meyer criticized the culturing of extracted teeth proposing the likely event that salivary contamination via normal oral flora occurred during extraction.[56, 95] Grossman later provided support that virtually all investigations and conclusions thereof regarding the pulpless tooth prior to 1936 were scientifically unsound.[56, 96]

In 1918 C.A. Peak responded to the ongoing, widespread, indiscriminate extraction of teeth due to the focal infection and elective localization theories. He stated, “The ruthless extraction of teeth, as demanded by some of the physicians, is a crime

against the patient, and indictment against the physician and the surgeon, and a sad commentary on the co-operation and understanding existing between the medical and dental professions."[56, 97] Although Rosenow did find it imperative to remove questionable teeth in the presence of systemic disease, he did not support thoughtless extraction. He stated:

> No one deplores more than I the ruthless extraction of teeth that has been practiced in some instances as a result of the work on focal infection. Vital teeth free from pyorrhea should never be extracted except as it becomes necessary for restorative work. The extraction of pulpless teeth seems to me to be indicated, regardless of the appearance of the radiograms, in cases of serious systemic diseases for which no other focus can be found.[56, 92]

However, he did not limit his extraction protocol to pulpless teeth. He stated, "Teeth, especially multi-rooted teeth, with deep fillings or caps, which manifest evidence of infection of the pulp, with or without pulp stones and even symptomless teeth which react positively to vitality test and that have deep fillings, may be the source of systemic effects, and my need to be removed." He did not support root canal therapy as protecting from elective localization, stating, "devitalization … and the filling of root canal … should cease."[56, 91]

Although, the popular practice continued to involve a tendency toward radical extraction of questionable teeth in attempt to alleviate systemic conditions, some astute individuals attempted to dispel the irresponsible and irrational treatment. W.L. Holman criticized the theory of elective localization with his review of literature in 1928. He stated, "The specificity of the bacteria has not been proved and the theory of elective localization is so open to misinterpretation and so limited in its practical application that it cannot be considered as a help in the solution to the problem. A certain general bacterial adaptation to environment is conceded by everyone, but the factors on the side

of the host are more variable and far more important."[56, 98] E.H. Hatton also vocalized his concerns by stating, "It is true that anyone can acquire much information from the study of dental roentgenograms, but to presume to arrive at a definite conclusion, solely from their examination, is a type of folly that no good physician would be guilty of in the study of any other part of the body." He suggested treatment of the pulp canal could be accomplished even after infection.[56, 99]

Thanks to scholars like Coolidge, Johnson, Rhein, Callahan, Grove, Prinz, and others who promoted emphasis on enhanced aseptic techniques, definitive diagnosis, bacteriological and histological methods, and universal radiographic practices, there was a pendulum shift away from the radical extraction practices of the "one-hundred percenters," and toward improved root canal therapy.[56, 68, 85, 100] In 1930 an editorial in *Dental Cosmos* stated, "The policy of indiscriminate extraction of all teeth in which the pulps are involved has been practiced sufficiently long to convince the most rabid hundred-percenter that it is irrational and does not meet the demands of either medical or dental requirements, and much less those of the patient."[85, 101] Although there was a definite change in philosophy occurring, it would take approximately 10 years until a more conservative approach to the treatment of the pulpless tooth would gain wide acceptance in practice.[85] Unfortunately, the focal infection is not dead even today. Some medical professionals will adopt one or more of its aspects when diagnosis is indefinite or treatment unsuccessful despite the fact that the theory is scientifically invalid.[56]

At the close of the focal infection debate, an additional theory was proposed by U.G. Rickert and C.M. Dixon in 1931 describing a "hollow tube effect."[85, 102] Their experimentation revealed "halos of irritation" around the open ends of implanted

platinum and steel hypodermic needles. In their opinion this was evidence that "the circulatory elements diffusing out of the openings of these tubes were not well tolerated by the vital tissues."[56, 102] They related this to a root canal hypothesizing that a void left in a root canal filling could allow for the space to be occupied by tissue fluids leading to enzymatic breakdown even in the absence of microorganisms. This breakdown could lead to products with capability of eliciting the inflammatory response in periapical tissues.[85, 102] They advocated an absolute requirement for a tight seal of the root canal with a material that could not irritate the periapical tissues. The recommendation to minimize local tissue irritation is legitimate, but the "hollow tube theory" was disproved by M. Goldman and A.H. Pearson,[103] C.D. Torneck,[104] and J.M. Phillips[105] in the 1960s.[56]

Throughout the years of the controversy surrounding the focal infection and hollow tube theories, there were multiple endodontic innovations. B.W. Herrman began using calcium hydroxide for root canal fillings in 1920 at the same time condemning the use of "foreign" medications such as phenol, tricresol-formol, paraformaldehyde, and camphor. In 1929 the histologic studies of Balint Orban demonstrated the presence of cells of defense and repair in the pulp tissue suggestive of profound ability to heal.[78, 85] This paved the way again for Herrman in 1930 who showed that a vital, amputated pulp covered with calcium hydroxide could form a bridge of secondary dentin.[85, 106]

In 1925 U.G. Rickert described an early derivative of the lateral condensation technique in which he suggested the use of a gutta percha cone in conjunction with a cementing medium. He recommended a single cone be pressed into place in order to extrude sealer through the convoluted accessory canal anatomy. Later, an instrument would be designed allowing lateral compaction of gutta-percha and facilitating the

placement of additional cones.[78, 85] Later that year, Henri Lentulo introduced his rotary paste inserter, which Rickert advocated for use in carrying sealer to the root canal system.[85, 106] In 1933 Dr. E.A. Jasper introduced standardized silver points used for filling root canals that possessed the same diameter and taper as reamers and files and were often used with Neo-balsam cement.[68, 85]

The years of 1937 to 1963 are known as the scientific era of endodontics. During this period, scientific evidence based on sound histological, biological, and pathological findings was used to drive root canal therapy and support treatment decisions.[85]

In 1937 C. Hammond and R. Tunnicliff isolated the presence of bacteria in the pulps of extracted teeth that were devoid of inflammatory tissue changes.[85, 107] In 1940 R.F. Sommer and M.C. Crowley concluded that no correlation could be derived between bacteriological status of the pulp cavity and the radiographic appearance of periapical lesions. They also indicated that radiolucency does not automatically equate to infection. These findings were later supported by F.T. Wais in 1958, who further discredited the correlation between the type of radiographic lesion and histopathologic findings.[85]

Near the end of World War I, new chemotherapeutic agents emerged in the treatment of root canals and periapical infections.[85] Specifically, 0.5-percent solutions of sodium hypochlorite, which were used in wound debridement on the battlefield, were implemented into the root canal cleaning regimen.[108] Fred Adams is credited the first usage of penicillin as an intracanal medicament in 1944.[78, 85] In 1948, L.I. Grossman introduced a penicillin suspension for root canals followed by a penicillin-streptomycin suspension. He then introduced the popular penicillin-streptomycin-bacitracin-sodium caprylate suspension (PBSC) in 1949, which he would apply via absorbent points to

"sterilize" the root canals.[56, 69, 85, 109] Further research revealed that chemotherapeutic agents were unable to completely eradicate all microorganisms from a root canal. Also, resistant strains of microorganisms to penicillin began to surface. M.B. Auerbach used this information in 1953 to re-emphasize the importance of thoroughly cleaning and shaping of the root canal system. His work led to the acceptance of a combination of instrumentation with medication, in a process later known as chemomechanical debridement.[85]

In 1943 a group of dental professionals with the common interest of root canal therapy met in Chicago to form the American Association of Endodontics (AAE). The term endodontic is derived from the Greek word "en," meaning in or within, and "odous," meaning tooth. Harry Johnston is credited for coining the term, which was virtually nonexistent prior to this time. In 1928, his practice "limited to endodontics," was credited as the first of its kind.[56, 85] The AAE formed a committee in 1949 driven to establish a specialty board in endodontics, and the American Board of Endodontics was organized in 1956.[85, 110]

The *Journal of Endodontia* was the first dental journal strictly devoted to endodontics and was first published in 1946.[85, 111] It was discontinued in 1948, but through a deal with the C.V. Mosby Co. a section limited to endodontics was allotted in the *Journal of Oral Surgery, Oral Medicine, and Oral Pathology*.[85]

In 1959 Sargenti and Richter introduced N_2, a medicament and sealer containing 6.5-percent paraformaldehyde, lead, mercury, and other questionable agents, to the American dental community. Supporters claimed that it neutralized connective tissue remnants within the pulp cavity and that it was impossible for a granuloma to form a root

filled with N_2. Proponents also suggested that root canals overfilled with N2 would not illicit a long-term inflammatory response.[85, 112] Many authors later cited evidence of *in-vivo* toxic effects of one or more of the ingredients on pulp and periapical tissues and with overextension being shown to result in osteomyelitis and paresthesia.[113-116] Also, the claims of profound and extraordinary antiseptic properties were disproved by the Council on Dental Therapeutics of the American Dental Association in 1962.[117]

In 1963 the American Dental Association (ADA) recognized endodontics as a specialty of dentistry. At that time, there were more than 200 dentists limiting their practice to endodontics. The first examination and certification of Diplomates took place in 1965.[56, 85]

That same year, Kakehashi, Stanley, and Fitzgerald changed the world of endodontics forever. Their groundbreaking study examined the effects of surgical exposures of dental exposures of dental pulps in germ-free and conventional rats and showed that in order for pulpal disease to occur and progress, bacteria must be present. Thus, it was determined that the ultimate aim of endodontic therapy should center on treatment modalities that completely disinfect the root canal system, a goal which is still sought today.[9]

ENDODONTIC THEORY

The main objective of endodontic therapy is to treat pulpal and periradicular tissues in order to retain the natural dentition so that normal form, function, and esthetics will be maintained.[1-3] From a physiology standpoint, root canal therapy is directed to prevent periradicular periodontitis.[1-5] Periradicular periodontitis is defined as inflammation, often with destruction, of periodontium that may or may not produce

clinical symptoms.[6] In order for this inflammation to be of endodontic origin, the pulp has been inflamed or infected to a point at which byproducts have permeated through the apex, lateral or accessory canals, or dentinal tubules to trigger an inflammatory vascular response in the periodontium.[8, 9] This response is primarily caused by pathogenic microorganisms such as bacteria, fungi, and viruses.[3, 9-17] Second, there are also non-living materials such as dentin and cementum chips as well as foreign debris that directly or indirectly illicit an inflammatory response.[3] Specifically, multiple studies illustrate a direct relation between intracanal bacterial load and healing prognosis post-endodontic therapy.[9, 18-20] Thus, the main goal of all endodontic procedures is to remove canal contents, specifically living, infectious, microorganisms as well as necrotic and vital organic tissue.[1-5, 9, 21]

One of the key methods in removing canal contents is by cleaning and shaping the root canal system.[1-3] This includes mechanically debriding the canal space, creating a reservoir to facilitate the delivery of disinfecting irrigation solutions and medicaments, and modifying the three-dimensional anatomy to accommodate effective obturation.[1-3, 22]

In 1955 G.G. Stewart divided root canal therapy into three phases: chemomechanical preparation, microbial control, and obturation of the root canal. He emphasized that chemomechanical preparation is probably the most important phase of the process as the other two phases are largely dependent on its successful completion. During the process of chemomechanical preparation, files are used to systematically increase the size of the root canal system. As the canal diameter is increased, infected tissues and contaminated dentin from canal walls are planed away by direct contact. The number of microorganisms present is reduced and debris is also removed, which

minimizes sources for the growth of residual microorganisms. The increase in canal volume allows for a maximum volume of irrigation solution and medicament delivery to most apical extents of the canal while facilitating more efficiency in debris evacuation. Lastly, obturation is more easily facilitated by an enlarged canal, allowing for its optimal condensation and ability to seal.[118]

In 1965 Kakehashi, Stanley, and Fitzgerald[9] examined the effects of surgical exposures of dental exposures of dental pulps in germ-free and conventional rats and showed that for pulpal disease to occur and progress, bacteria must be present.

In 1967 L.I. Grossman[119] agreed with Stewart that biomechanical instrumentation supports the removal of microorganisms and debris while creating a specific shape of the root canal to facilitate the best possible obturation. He also expanded upon the three phases of root canal therapy introduced by Stewart with the creation of 13 tenets that he deemed mandatory during any root canal procedure:

1) Implement an aseptic technique.
2) Maintain instruments within the root canal.
3) Never force instruments apically.
4) Enlarge canal space beyond its original size.
5) Continuously irrigate the root canal system with an antiseptic.
6) Maintain all solutions within the canal space.
7) Fistulas do not require special treatment.
8) Obturation of the root canal to take place only after a negative culture obtained.
9) Provide a hermetic seal of the root canal system.

10) Only use obturation materials that are non-irritating to the periapical tissues.

11) Establish proper drainage in the presence of an acute alveolar abscess.

12) Avoid injections into infectious areas.

13) Apical surgery may be required to promote healing of the pulpless tooth.

According to H. Schilder in 1967, the ultimate goal of endodontic therapy is to render the root canal system free of diseased tissue and contents in order to alleviate periapical inflammation and infection. He also suggested that only when the root canal system is sealed from the periodontal ligament and surrounding bone can the breakdown of the attachment apparatus be halted and healthy periodontium re-established. Schilder recommended chemomechanical preparation of the root canal system with instruments and antiseptics followed by the three-dimensional obturation terminating at the cementodentinal junction or 0.5 mm to 1 mm from the radiographic apex.[5]

In 1983 T.R. Pitt Ford expanded upon the importance of the three-dimensional filling of the root canal system proposed by Schilder as he outlined the objectives of obturation:[120] 1) Diminish the space available to colonize bacteria; 2) Prevent the contamination of the apex after extirpation of the pulp; 3) Prevent the movement of bacteria along the canal walls.

In 1996 F. Weine also placed the primary emphasis of root canal therapy on chemomechanical preparation, indicating that only when properly cleaned and shaped should the canal be hermetically sealed with an inert obturation material. He outlined a summary of endodontic principles:[121]

1) The objective of endodontic therapy is restoration of the treated tooth to its proper form and function in the masticatory apparatus in a healthy state.

2) The three phases of root canal therapy are diagnosis, canal preparation, and obturation to the level of the cementodentinal junction.
3) When a canal is properly cleaned and shaped, any accepted method of obturation will probably result in success.
4) The use of a rubber dam should be considered mandatory to protect the patient and prevent contamination of the root canal system.
5) All instrumentation and filling materials should remain completely within the root canal system.
6) All endodontically treated teeth should be properly restored to prevent coronal leakage.
7) The patient should be observed postoperatively to evaluate the status of healing.
8) Case presentation should be provided to the patient.

Although much emphasis of root canal therapy is placed on successful chemomechanical preparation and three-dimensional obturation of the root canal system, the quality of the coronal restoration plays a major role in the success of endodontically treated teeth. A coronal restoration of sound structural and marginal integrity is required to prevent the re-infection of the root canal system via salivary contamination. When H.A. Ray and M. Trope evaluated 1010 teeth with varying qualities of coronal restoration and root canal obturations, they found that the quality of the coronal seal was the most important factor in preventing the presence of periradicular inflammation (PRI).[122] In 2006 Yamauchi et al. examined effect of IRM and composite orifice plugs on coronal leakage. Beagle premolars were obturated in vivo with gutta-percha and AH-26 sealer.

The access openings were left open to the oral environment for eight months. Upon histologic evaluation of the periapical regions, periapical inflammation was observed in 89 percent of the group without orifice plugs and in 39 percent of the group with orifice plugs. This significant reduction in apical periodontitis further emphasizes the importance of protecting the obturated root canal system with a restoration free from coronal leakage.[123]

SUCCESS OF ENDODONTIC THERAPY

Multiple studies exist in the literature appraising the success of root canal therapy. It is imperative for the endodontist to be well-versed to compare alternative treatments and implement an individualized treatment plan according to research-based evidence. Only then will the clinician and patient have the utmost confidence that the selected treatment is the most appropriate.

The classic study undertaken at the University of Washington School of Dentistry[124] is one of the most comprehensive studies examining endodontic success and failure as well as its influencing factors. A total of 3678 patients were contacted via mail to participate in a "free x-ray" at follow-up intervals of six months, one year, two years, and five years after non-surgical or surgical endodontic therapy was performed. The two-year study group proved most ideal, because periradicular repair was often not completed for the middle-aged and elderly patients within one year, and only 302 cases returned at five years. There were a total of 1229 patients who actually returned at two years, which accounted for 33.41 percent of the original study population. Recall radiographs were evaluated. Cases that exhibited periradicular improvement were deemed successes, and cases that demonstrated an unimproved or deteriorated periradicular status were deemed

failures. The overall success rate of non-surgical root canal therapy at the two-year follow-up was 91.54 percent. Although examiners found multiple etiologies of root canal failure, incomplete obturation accounted for 58.66 percent, which was statistically significant. Some other causes of failure included but were not limited to, in descending order of frequency: root perforation (9.61), external root resorption (7.7 percent), coexistent periodontal-periradicular lesion (5.78 percent), canal grossly overfilled or overextended (3.85 percent). Surgical endodontic treatment was also evaluated at two year follow-up providing a success rate of 92.88 percent.

A similar study was performed at West Virginia University School of Dentistry from 1959 to 1979 to determine the degree of success or failure of conventional root canal therapy.[125] Recall radiographs and clinical examinations were performed at six months, 1 year, 2 years, 5 years, and 10 years after standardized root canal treatments were performed. The following criteria were required for a case to be considered successful: 1) Pain or swelling was absent; 2) Any sinus tracts disappeared; 3) Function was not lost; 4) Radiographic rarefaction displayed arrest or resolution after one year.

Of the 1007 endodontically treated teeth examined, 89.66 percent were considered successful. Teeth that presented with radiographic rarefaction at time of initial treatment had a significantly lower success rate of 82.91 percent compared with 94.22 percent success rate in cases without pre-existing radiographic rarefaction. Also, root canals that were overfilled showed a significantly lower success rate of 63.41 percent as compared with the success rates exceeding 89 percent seen in canals that were obturated flush with the radiographic apex or short of ideal working length. It can be stated that overfilled root canals were four times as likely to fail as those filled flush with or short of

radiographic apices. Lastly, teeth with improper restorations showed a significantly higher number of root canal failures than those in which proper restorations were implemented.[125]

The Toronto Study[126] examined 405 endodontically treated teeth over a four- to-six-year follow-up period to assess treatment outcome. Re-evaluation was performed by an independent examiner who performed clinical and radiographic assessments. Overall, the study concluded that 81 percent of teeth were "healed" after endodontic therapy. More important and similar to previous studies, endodontic treatment proved to be significantly less successful (74 percent) when apical periodontitis was present as compared with the presence of a normal periapex (92 percent) at the time of initial treatment.[126]

In 2001 Lazarski, et al.[127] performed an epidemiological evaluation of a large pool of insured dental patients to determine the outcomes of nonsurgical root canal therapy. The data were obtained from Delta Dental Plans Association, Seattle, WA, which maintained a computerized database of claims serving approximately 1.5 million patients. Of these patients, 110,766 had non-surgical root canal procedures performed, with 44,613 patients returning within the two-year follow-up period for extraction (5.56 percent), retreatment (2.47 percent), or periradicular surgery (1.41 percent). The incidence of extraction increased with the increasing age of the patient and in teeth that were not restored after root canal therapy. The data revealed that 94.44 percent of endodontically treated teeth remained functional over an average follow-up period of 3.5 years.[127]

Salehrabi and Rotstein[128] performed an epidemiological study in 2004, similar to Lazarski, to assess the outcome of endodontic treatment across the US. Endodontic

treatment was performed by endodontists and general practitioners on 1,462,936 teeth of patients with the Delta Dental Insurance plan. After completion of the non-surgical root canal therapy, the teeth were tracked in the database over a period of eight years, analyzing for submission of ADA codes indicative of retreatment, extraction, or surgical endodontic procedures. Overall, the authors found that 97 percent of teeth were retained in the oral cavity upon recall. Most untoward events occurred within three years from completion of initial endodontic treatment. Of the extracted teeth, 85 percent were never restored with full cuspal coverage, and non-covered endodontically treated teeth were statistically more prone to failure.[128]

Multiple studies support endodontic therapy as a successful treatment modality in the preservation of natural dentition. However, various factors may deem a recommendation for root canal therapy unfeasible, irresponsible, or less than ideal. Thus, it is important that the practicing endodontist be aware of alternative treatment options as well as predicted their comparative predicted prognostic values so the most appropriate and ethically-sound treatment can be advised.

In 2006 Doyle et al.[129] devised a retrospective cross-sectional comparison of the outcomes of single-tooth implant restorations versus matched teeth receiving non-surgical root canal therapy with restoration. An outcome of success, survival, survival with subsequent treatment, intervention, or failure were assigned to 196 implant restorations, and 196 matched teeth in which nonsurgical root canal treatment was performed. There was no statistically significant difference between the percentage of teeth in each of the four categories in either treatment group. The authors concluded that single-tooth implant restorations and restored endodontically treated teeth have similar

failure rates. The implant group exhibited an extended median duration from placement to function as well as a higher incidence of postoperative complications mandating future treatment.[129]

In 2007 Torabinajad et al.[130] performed a systematic literature review of MEDLINE, Cochrane, and EMBASE databases to compare the outcomes of root canal treatment and restoration, implant-supported single crowns, fixed partial dentures, and extraction without tooth replacement. Of the 143 selected studies a direct comparison of outcomes was extremely rare and relatively impossible due to variable design, success definition, assessment methods, operator type, and sample size. However, long-term survival rates for restored endodontically treated teeth and implant-supported single crown were similar with success and survival rates in both groups proving superior to those of fixed partial dentures. Although these results support endodontic therapy and implant placement as successful therapeutic interventions, clinical trials with large sample sizes examined over extended periods of time with well-defined outcomes criteria are essential for future prognostic comparison.[130]

CANAL ANATOMY

The astute endodontist must possess an extensive knowledge of common root canal morphology as well as its frequent variations to promote success of endodontic therapy. Lack of working knowledge of pulp anatomy is arguably one of the leading causes of treatment failure behind inadequate diagnosis and treatment planning. It is imperative that knowledge of root canal anatomy be three-dimensional as most teeth possess anatomic variation including but not limited to multiple foramina, additional canals, deltas, fins, loops, intercanal connections, C-shaped canals, and furcation and

lateral canals. The clinician must be well versed in the multiple possible pathways root canals can take to the apex, understanding that the canals may branch, divide, and rejoin creating a convoluted system. Only then can an effective treatment plan be formulated, and the best possible endodontic therapy implemented.[131, 132]

G.V. Black[133] is credited as one of the initial dental professionals to formally discuss root canal anatomy. In his 1890 book, *Descriptive Anatomy of Human Teeth*, he provided illustrations of internal canal configurations derived from personal observation of actual tooth sections. Unfortunately, limitations in magnification and imprecise sectioning modalities did not allow for the discovery of minor variations in canal anatomy and suggested that canals were relatively cylindrical in shape. This generalized perception of simple root canal anatomy was largely maintained in popular belief until the revolutionary study published by Hess in 1921.[134] Canal spaces of extracted teeth were pressure-injected with vulcanized rubber leaving an impression of the canal system after teeth were decalcified. Examination of these impressions revealed the highly variable, convoluted nature of the internal root canal scheme.

In 1969 Weine et al.[135] sectioned 208 mesiobuccal roots of maxillary first molars to determine canal configuration and incidence of an additional canal. A coarse sandpaper disk was used to section roots in the buccolingual direction in an attempt to include the entire length of the canal(s) from the roof of the pulp to the apex. The canal configurations were summarized into three general categories:

1) Type I was a single canal extended from the pulp chamber to the apex.
2) Type II was a larger buccal canal and a smaller palatal canal merged 1 mm to 4 mm from the apex.

3) Type III was a larger buccal canal and a smaller palatal canal existed separate with distinct apical foramina.

These categorizations were later modified by Weine[121] in order to create an applicable classification system for determining canal configuration for any one root of the 32 permanent teeth. This Weine classification system is still used today:

1) Type I exhibits a single canal from the pulp chamber to the apex.
2) Type II exhibits to separate canals leaving the chamber but merging prior to forming one canal at the apex.
3) Type III exhibits two separate canals leaving the pulp chamber that remain separate and exit via separate apical foramina.
4) Type IV exhibits one canal leaving the pulp chamber that divides into two separate and distinct canals short of the apex to terminate at two separate apical foramina.

In 1984 Vertucci[136] introduced a more extensive canal classification system after investigating the root canal anatomy of 2400 human permanent teeth. His methods for root dissection differed from Weine, in that extracted teeth were decalcified, injected with dye, dehydrated, and cleared for microscopic examination. The results yielded an eight-type root canal classification system commonly used today and outlined below:

1) Type I is a single canal from the pulp chamber to the apex.
2) Type II exhibits two separate canals exiting the pulp chamber that join prior to forming one canal at the apex.
3) Type III exhibits one canal exiting the pulp chamber that separates into two prior to merging again to terminate as one canal.

4) Type IV exhibits two separate and distinct canals from pulp chamber to apex.
5) Type V exhibits one canal exiting the pulp chamber that divides prior to reaching the apex and terminates as two separate apical foramina.
6) Type VI exhibits two separate canals leaving the pulp chamber that join in the body of the root and split again prior to reaching the apex where they terminate as two distinct canals.
7) Type VII exhibits one canal leaving the pulp chamber that divides and then reconnects within the body of the root, and separates again into two distinct canals short of the apex.
8) Type VIII exhibits three separate canals seen from pulp chamber to apex.

Pineda and Kuttler[137] used a radiographic method to determine normal root canal anatomy and its variations and percentages because radiographs are utilized clinically during endodontic therapy to analyze the root canal system. The 4183 teeth collected were classified into three groups according to age of the patient at extraction. All teeth were radiographed in the mesiodistal and buccolingual directions. Radiographs of 7275 root canals were evaluated on a light-box with the adjunct of a magnifying glass. Approximately 3.0 percent of all canals were straight in both buccolingual and mesiodistal dimensions, and mostly represented maxillary central incisors. These curvatures were evident in apical, middle, and cervical thirds of the root canal system, with the first being the most prevalent. Curvatures were also evident in the distal, mesial, and buccal directions. Approximately two-thirds of canals were narrow and significantly curved with the other one-third being curved but moderate in diameter. The main canal exhibited ramifications in 30.6 percent of cases studied. Although these ramifications

were observed in the middle and apical thirds, the latter occurred more commonly. The apical third of the canal also often exhibited a larger diameter in the buccolingual dimension. Ramifications were not seen in multi-rooted teeth in associated with bifurcation or trifurcation areas. The foramen of the main root canal was located to one side of the apex in 83 percent of cases, sometimes to a distance of 2 mm or 3 mm. Although deltas were found, they were rare and did not seem to affect endodontic treatment. The authors concluded that radiographs depict a poor two-dimensional representation of a three-dimensional canal system that is extremely convoluted and constantly evolving with increasing age of the patient.

In addition to possessing an extensive knowledge of the variation in canal numbers, routes, and their frequencies within a given root, it is also imperative to gain a comprehensive and precise understanding of the topographic and microscopic anatomy of the root apex.

Edward Green[138] microscopically examined 300 root canals of 110 from extracted human posterior teeth to determine cross-sectional diameters. The roots were sectioned 90-degrees to the root canal at 0.5 mm to 1.0 mm and 5 mm to 6 mm from the apical foramen. Specimens were measured with the adjunct of a micrometer-measuring microscope. Approximately 1200 measurements led to the author's conclusions:

1) Maxillary first premolars possessed buccal and palatal canals of similar canal size close to the apical foramen as well as 5 mm to 6 mm from it.
2) The distobuccal canals of maxillary first molars were larger than mesiobuccal canals, especially at a distance of 6 mm from the apex.

3) The mesiobuccal canals of maxillary second molars were larger than the distobuccal canals.
4) The mesiolingual canals of mandibular molars were smaller than the mesiobuccal canals, especially near the apex of second molars. However, approximately 6 mm from the apex, the mesiolingual canals were larger than the mesiobuccal canals.
5) Maxillary first molars exhibit larger palatal root canals than that of maxillary second molars.
6) Mandibular first and second molars possess root canals of similar size close to the apex, but were smaller 6 mm from the apex of first molars.

In 1955 Kuttler[139] examined the apices of 402 extracted cadaver teeth with an ocular microscope after sectioning. Teeth were grouped according to the age of the teeth with group one consisting of teeth extracted from cadavers between the ages of 18 and 25, while group two consisted of teeth extracted from cadavers over the age of 55. The center of the principal foramen deviated from the apical vertex in 68 percent of roots from group one, and in 80 percent of roots from group two. The average distance between the center of the foramen and the root vertex was 0.50 mm in group one and 0.61 mm in groups two, suggesting that the foramen diverges more from the root vertex with increasing age and resulting cementum deposition. The average canal diameter at the junction of the cementum and dentin ("cement-dentinal canal" later termed cement-dentinal junction) was approximately 0.30 mm in group one and 0.27 mm in group two. However, group one exhibited an average foramen diameter of 0.50 mm while group two revealed an average of 0.68 mm, again most likely due to increased cementum deposition

with age. Thus, it was shown that most root canals exhibit a minor diameter at the cement-dentinal junction (CDJ) that gradually funnels out to a maximum diameter at the foramen. This funnel-like aspect is more pronounced in older teeth due to a larger foramen diameter as a result of years of cementum deposition and a smaller canal diameter as a result of long-term dentin deposition. The author concluded that due to this funnel-like design, the canal cannot be hermetically obturated unless it is overfilled with cement. Due to an average cementum deposition of greater than 0.5 mm in group one and even greater in group two, the CDJ averaged 0.52 mm from the foramen in the former and 0.66 mm in the latter. These findings, along with knowledge of the orientation of apical cementum and dentin promoted Kuttler's suggestion for obturating the root canal no less than 0.5 mm from the foramen, seemingly to approximate the minor diameter of canal or cemento-dentinal junction.[139]

David Green[140, 141] introduced two classic studies in which anterior and posterior root apices were evaluated with a stereomicroscope. The examination of 400 anterior teeth was published in 1956[140] followed by the evaluation of 700 posterior teeth in 1960.[141] Specimens were evaluated and measured at X20 magnification, using a calibrated micrometer disc inserted into the eyepiece receptacle. The average diameter of the major foramina was 0.40 mm for the 150 maxillary anterior teeth and 0.30 mm for the 250 mandibular anterior teeth. However, major foramina diameters of posterior teeth ranged from 0.30 mm in maxillary first premolars to 0.65 mm in the distal root of mandibular molars. The average minor foramina diameter of all 400 anterior teeth was 0.20 mm and ranged from 0.15 mm in maxillary premolars to 0.25 mm in the palatal root of maxillary molars. The average distance of all major foramina from their apex in

anterior teeth ranged from 0.20 mm to 0.35 mm and between 0.30 mm to 0.45 mm in posterior teeth. However, the average distance of all minor foramina from ranged between 0.40 mm in mandibular incisors and 2.2 mm in maxillary incisors. The posterior teeth averaged between 0.80 mm and 1.0 mm from minor foramina to their apex. Green also concluded that the average "funnel-like" aspect of the canal, previously discussed by Kuttler[139], shrinks to 50 percent of its diameter approximately 0.75 mm from the surface opening and seemingly represents the minor constriction of the canal.[140, 141]

Multiple authors have published similar studies to that of Kuttler[139] and David Green with variable results.[140, 141] In 1972, Burch and Hulen[142] stained the roots of 872 teeth and examined them under X28 magnification to determine the relationship of the apical foramen to the anatomic apex. The authors concluded that 92.4 percent of the major foramina opened short of the anatomic apex with an average of 0.59 mm from the anatomic root vertex. In 1984, Dummer et al.[143] evaluated 270 extracted human teeth with an X20 microscope to determine the position and topography of the apical canal constriction and foramen. The average distance from foramen to apex was ranged from 0.23 mm in maxillary incisors to 0.47 mm in mandibular canines providing an overall mean of 0.38 mm. The average distance from canal constriction to apex ranged between 0.79 mm in mandibular incisors to 0.99 mm in mandibular premolars with an overall average of 0.89 mm. In some instances, multiple constrictions were observed or altogether absent. The author concludes that it is impossible to predictability establish the precise position of the apical canal constriction and recommends implementing a combination of multiple methods for most accurate approximation.[143]

In addition to acquiring a vast knowledge of canal anatomy in the body and apical regions of the root, the clinician must also be well-versed in the typical patterns and rare variations in anatomy of the pulp-chamber floor. In 2004, Krasner and Rankow[144] sectioned 400 teeth horizontally at the cementoenamel junction (CEJ), 50 mesiodistally, and 50 buccolingually. Two independent examiners evaluations of patterns in orifice location, color, shape, and size led to the following conclusions:

1) Law of Centrality: The pulp chamber floor is always positioned in the center of the tooth at the level of the CEJ.
2) Law of Concentricity: The internal pulp anatomy always resembles the external anatomy of the tooth with chamber walls concentric to the external surface at the level of the CEJ
3) Law of the CEJ: The distance from the wall of the pulp chamber to the external surface of the crown is consistent throughout the circumference of the tooth at the level of the CEJ.
4) Law of Symmetry 1: With exception of maxillary molars, the distances between canal orifices is equal from a line drawn in a mesial-distal direction through the floor of the pulp chamber.
5) Law of Symmetry 2: With the exception of maxillary molars, the canal orifices area positioned on a line perpendicular to a line drawn in a mesial-distal direction across the center of the pulp chamber floor.
6) Law of Color Change: The pulp chamber floor is always darker than the walls.

7) Law of Orifice Location 1: The root canal orifices are always located at the chamber wall-floor interface.
8) Law of Orifice Location 2: The root canal orifices are located at the angles in the floor-wall junction.
9) Law of Orifice Location 3: The root canal orifices are positioned at the termination of the root developmental fusion lines.

Knowledge of pulp-chamber anatomy will allow for creation of an ideal access opening in which all canals be located, straight line access established, and pulp chamber deroofed all while conserving as much tooth structure as possible. Once these objectives have been met, instrumentation can be initiated and chemomechanical debridement facilitated.[1]

INSTRUMENTATION

The main goal of all endodontic procedures is to remove all canal contents, including necrotic and vital organic tissue, dentinal chips/debris, and all microorganisms in order to prevent apical periodontitis.[2, 4, 21] One of the key methods in removing root canal contents is by cleaning and shaping the root canal system via hand and rotary instrumentation. This includes mechanically debriding the canal space, creating a reservoir to facilitate the delivery of disinfecting irrigation solutions and medicaments, and modifying the three-dimensional anatomy to accommodate effective obturation.[2, 22, 145] A plethora of root canal instruments and preparation techniques have been described in the literature, but all require instruments to plane the root canal walls to facilitate adequate debridement.[30, 146]

Multiple endodontic instruments have been designed for the various procedures performed within the pulp chamber and root canal system. The instruments utilized for the purposes of root canal preparation can be classified into three groups.[147] Group One includes manually operated instruments, such as K-type and H-type instruments. Group Two includes engine-driven instruments possessing a latch-type of attachment as part of the working section intended to be attached to and driven by a low-speed dental handpiece. Gates Glidden (GG) burs are a classic example. Group Three includes engine-driven instruments similar in design to the manual instruments, but with the handles replaced with attachments for a latch-type of dental handpiece. Nickel-titanium rotary files are a classic example.

Manual root canal instruments were first introduced in the early to mid-nineteenth century and remained the primary devices of root canal preparation up until the late 1980s. The Kerr Company created the K-type instruments in the early 1900s, which reside as the oldest useful instruments for cutting and machining dentin.[30, 147] These instruments are fabricated by grinding a tapered stainless steel wire to establish tapered square or triangular cross-section. The ground wire is then twisted to create a file or reamer with the former having more flutes and less space between the flutes than the latter. These instruments penetrate and enlarge root canals by compression-and-release destruction of the dentinal walls. The K-type file possesses an ability to cut upon clockwise and counterclockwise rotation as upon well as insertion and withdrawal. The H-type instruments are ground from a tapered stainless steel blank. Specifically, the Hedstrom file, a specific type of H-type file, is formed by grinding a single continuous flute. These H-type instruments possess spiral edges with angles facing the handle of the

instrument that only allow cutting during withdrawal. The positive rake angle of the flutes is responsible for the enhanced cutting efficiency when compared with K-type files. The manual instruments remain crucial components of all root canal instrumentation procedures.[147]

The Gates-Glidden drills were introduced in 1885.[30] These stainless-steel, engine driven instruments are attached to a low-speed dental handpiece via a latch-attachment. The instrument exhibits a long, thin, cylindrical shaft with parallel walls and a short cutting head. This elliptically-shaped cutting head allows for the efficient removal of dentin in the coronal and middle aspects of the canal to facilitate straight-line access. Gates-Glidden drills are available in lengths of 15 mm and 19 mm with tip diameters ranging from 0.4 mm to 1.4 mm. These instruments are easy to remove in the event of separation because a fracture-point is mechanically incorporated high in the shank region. The clinician must exhibit special care to avoid attempting to instrument laterally or beyond curvatures as perforation is a realistic risk, especially in furcation areas. Overall, the Gates-Glidden burs are inexpensive, safe, and clinically effective.[147, 148]

Rotary-instrumentation of the root canal dates back to 1889 when Rollins created the first endodontic handpiece.[30] Structural limitations of steel instruments led to a high incidence of procedural accidents, and manual instrumentation prevailed as the primary mode of root canal preparation for almost a century. However, rotary-instrumentation of the root canal system was repopularized in the early 1990s with the introduction of nickel-titanium endodontic instruments.[149] The alloy proved to be more flexible and resistant to torsional fracture than stainless steel, allowing for greater instrument control in small, curved canals. These favorable characteristics have led to the creation of

countless file systems exhibiting various designs and shapes. A variety of instrumentation techniques have also been advocated and are largely dependent on the file system employed.[147, 148] While manual instruments are a basic necessity for all root canal preparations, nickel-titanium rotary instruments and advanced preparation techniques can circumvent some of the major shortcomings of traditional instruments and devices. [30]

Ingle[150, 151] advocated the standardization of endodontic instruments as early as 1955, but it was not until 1976 that the first approved American Dental Association (ADA) specification (number 28) was published. The ADA along with the American National Standards Institute (ANSI) designed a specification package that slightly modified Ingle's original recommendations. The International Standards Organization (ISO) and the Federation Dentaire Internationale (FDI) used the ADA proposal as a model for the creation of international specifications.[147, 152]

In 1961 Ingle[56, 150] joined others promoting standardized endodontic instruments and introduced the "standardized technique" to effectively clean and shape root canals. This technique was inspired by Seidler,[153] who envisioned the ideal canal preparation as being round and tapered. Ingle recommended reamers to enlarge the three or four mm of "round, tapered apical cavity with a minimal opening at the foramen," and files to finish the ovoid segment of the canal. Larger instruments could be utilized as long as the root canal was "comparatively large." The canal preparation was to terminate 0.5 mm from the apex.[150]

In 1969 Clem[30, 154] discussed the step-back technique for apical preparation. First, the body of the canal is shaped. The apical aspect of the canal is prepared, starting with a

small file and sequentially increasing file size. The initial file that binds slightly at the apex is deemed as the master apical file (MAF). Instrumentation length is sequentially decreased as instrument diameter is sequentially increased by standardized increments of 0.5 mm or 1.0 mm to create taper and adequately blend the middle and apical thirds of the canal.[3, 154]

Later, Torabinejad[155] modified the step-back technique in his introduction of the passive step-back technique. Gates-Glidden drills or Peeso reamers were advocated to achieve adequate coronal flare prior to apical root canal preparation with manual files in attempt to prevent apical transportation of the root canal. Instead of using arbitrary incremental decreases in instrumentation levels, the technique relies on the canal morphology to dictate the preparation shape. Successively larger sized instruments were only inserted to a point of first contact. The file was then rotated one-half turn clockwise and retracted from the canal. This entire process was repeated until a uniformly tapered preparation was created. The author suggested that the technique provided an effortless means of passive and gradual enlargement of the root canal in an apical to coronal direction while reducing the risk of procedural accidents.[3, 155]

In 1970 Weine et al.[156] suggested an incremental technique to be implemented in the step-back technique when the next larger instrument cannot readily be negotiated to desired length in a root canal. The authors recommend trimming one mm from the tip of a standard manual file with scissors and reestablishing a bevel with a diamond fingernail file. This modification would increase the file size by 0.02 mm allowing for a smaller increment transition between successive files. It was suggested that this practice along

with preflaring the file would decrease the likelihood of procedural accidents such as ledge formation and perforation.

In 1974 Schilder[145] emphasized the importance of ideal cleaning and shaping the root canal system in order to three-dimensionally obturate a "sterilized" root canal system. He advocated essential mechanical and biological guidelines to facilitate successful root canal preparation that included the following:

1) The root canal preparation should exhibit a continuous taper from the cement-enamel junction to the apex.
2) The diameter of the root canal preparation should be wider at every point coronally and narrower at every point apically.
3) The root canal preparation should flow with the original canal space.
4) Transportation should be avoided so that the position of the apical foramen remains constant.
5) The apical opening of the canal should remain as small as possible.
6) Instruments should always remain confined to the root canal system.
7) In necrotic cases, extra care should be taken so that debris is not apically extruded into periapical tissues.
8) Success of root canal therapy hinges on the ability to remove organic debris from the canal system.
9) Single canals should be cleaned and shaped in one appointment.
10) Adequate space must be created to facilitate the delivery of intracanal medicaments.

The continuously tapered, flared root canal preparation was later advocated by Smith et al.[157] as a result of their retrospective, five-year success study. The authors provided three major reasons for the enhanced success of the preparation technique. First, the coronal and middle thirds of the canals were more adequately cleaned. Second, straight-line access permitted access to the apical portion of the canal for instrumentation and irrigation. Lastly, leakage was reduced coronally, apically, and via lateral canals facilitating more predictable and successful obturation.

In line with the principles outlined by Schilder,[145] in 1975, Coffae and Brilliant[158] published a study comparing the step-back technique to "traditional methods" to evaluate efficacy of tissue debridement in root canals. Freshly extracted mandibular molars were both instrumented to an apical size of No. 30 or No. 35. The roots were sectioned at distances of 1 mm, 3 mm, and 5 mm from the apex and submitted for histologic evaluation. The root canals that were prepared with the step-back technique exhibited statistically significant less residual tissue in the canal system, suggesting an enhanced debridement efficacy. Neither of the canal preparation techniques seemed to adequately remove tissue from isthmuses.

In 1976 Walton[159] published a similar study that histologically compared the relative effectiveness of filing, reaming, and step-back techniques of root canal preparation. Preparations were performed *in situ* on 52 teeth that were planned for extraction. The 91 root canals were classified by degree of curvature and randomly grouped for implementation of a specific instrumentation technique. The filed group was instrumented by teasing the file to working length and twisting it until bound, forcing the instrument against the walls upon withdrawal. This process was repeated with

successively larger files until the length of the file was covered with clean dentin shavings and the walls were smooth. A similar procedure was replicated for the reamed group, except the instruments were not intentionally forced against the walls upon withdrawal. The step-back group was instrumented first by inserting small files to working length and rotating. Instrumentation was continued with sequentially larger files until reaching a size in which the very apical portion of the file was clean. After establishing this master apical file, which was usually a No. 25 to No. 30, sequentially larger files were utilized to instrument the canal in 0.5 to 1.0 mm shorter lengths. This process was continued, filing the canal at shorter lengths with larger files ending with at least a number 60 file. Upon extraction and histologic evaluation, the following conclusions were drawn:

1) The step-back technique resulted in a statistically significant greater percentage of planed pulpal walls during root canal preparation.
2) Dentin was removed least effectively during root canal preparation in the filed group.
3) Regardless of preparation technique implemented, more of the straight to slightly curved canal walls were prepared as compared with the walls of the moderately to severely curved canals.
4) The canals of the step-back group were less uniform and rounded in shape than those of the filed and reamed groups, but more walls were planed and cleaned.
5) The canals in which clean, white dentin shavings and “smooth” walls were used to indicate the completion of instrumentation exhibited a wide variation

of the percentage of the canal that was actually planed and cleaned. These criteria were an invalid means of determining debridement efficacy.

In 1975 Weine et al.[160] published a study to determine the effect of root canal preparation procedures on the original shape of the canal and apical foramen. Clear polyester casting resin was poured around size No. 20, precurved, lubricated silver points that were imbedded in baseplate wax. The resin was polymerized and the silver points were removed. The simulated canal spaces were instrumented by 10 different practitioners implementing their native root canal preparation techniques. Photographs were acquired throughout the procedures for comparison. Regardless of the type of instrument or preparation technique all final preparations exhibited three undesirable characteristics. No preparation was completely funnel-shape from the orifice to the apex as the narrowest segment of the canal approximated the mid-curve area. This resulted in an hourglass appearance with the center termed the "elbow." All files inserted into the canal possessed a natural tendency to straighten inside even when precurved. The greatest amount of canal preparation took place at the outer portion of the curvature. As the file size increased, so did the amount of apical transportation. This phenomenon was unavoidable even with preflaring and redirection of the instrument under direct visualization.[160]

In 1980 Abou-Rass et al.[161] described the anticurvature filing technique to preserve the furcal wall, especially in the treatment of molars. Root canals in mesial roots of maxillary and mandibular molars are often located closer to the furcation than the center of the root. The furcal aspect of these canals was termed the "danger zone," as this area is more prone to strip perforation during overly aggressive enlargement of

preparation. Thus, the authors recommend removing dentin from the bulkier parts ("safety zone") of the canal wall towards the buccal, lingual, and proximal aspects.[3, 161]

Lim and Stock[162] compared the anticurvature filing to the standard step-back technique to assess possible differences in perforation risk potential in curved canals. After each of the 71 extracted mandibular molars was instrumented with one of the preparation techniques, the roots were sectioned at a distance of five and eight mm from the apex. Specimens were viewed under a microscope and measurements of minimum canal wall thickness were acquired with a micrometer. Anticurvature filing conserved a statistically significant greater amount of furcal wall thickness and reduced the perforation risk.

The step-down technique was described by Marshall and Papin[30, 163] in 1980 and Goerig et al.[164] in 1982 as a means of reducing the risk of extrusion of canal contents during instrumentation. The principles of the technique were largely influenced by a study published by Hession[165] three years prior. He concluded that canal contents are forced toward the apical foramen during instrumentation, and that this "piston-in cylinder" effect is amplified when the instrument size closely approximates the size of the canal. Hession recommended early canal flaring to produce a coronal escape-way for canal contents. In the step-down technique, Gates-Glidden drills were initially used to flare the coronal-third of the canal to remove coronal interferences and provide coronal taper. A large file was then progressed into the canal with a watch-winding motion until resistance was encountered. The file was replaced with successively smaller files, repeating the process until the working length was reached.

In 1983 Fava[166] described a modified version of the step-down technique, called the double-flare technique. Although, the technique presented slight modifications to the traditional step-down technique, the overall objectives and rationale were similar. The author recommended initially inserting a large enough file that slightly bound at the coronal one-third measurement of the canal. Instrumentation was then initiated in a step-down fashion, decreasing file size while increasing preparation length, until the superior aspect of cervical one-third of the canal was reached. After irrigating the canal, the working length was confirmed with a number 15 file. The step-down filing technique was continued until the confirmed working length was reached. Finally, the step-back technique was incorporated to enhance apical taper, and provide a smooth interface between apical and middle-thirds of the canal. The author also advocated the technique based on lack of post-operative flare-ups seen in any of the 30 devitalized root canals treated with this technique. However, the technique was contraindicated for calcified canals, young permanent teeth, or teeth with open apices.

In 1983 Leeb[167] who concluded that instrumentation difficulty is enhanced by the binding of instruments in the coronal aspect of an unflared canal. This inspired Morgan and Montgomery[168] to compare the crown-down (step-back) pressureless technique to the step-back filing technique relative to frequency of ledging, zipping, and perforation. Forty single-canal extracted human teeth with an apical curvature between ten and 35 degrees were chosen after radiographic examination from the faciolingual and mesiodistal aspects. Radiographs allowed for pairing according to degree of canal curvature and width. All teeth were mounted in a typodont prior to instrumentation. The canals of the first group of 20 teeth were prepared with the crown-down pressureless

(step-back) technique originally described by Marshall and Pappin.[163] The file that was two sizes larger than the one that initially reached true working length, or at least a number 25, was deemed the master apical file. The canals of the second group of twenty teeth were prepared using a step-back filing technique with precurved files. The file that was two sizes larger than the one that initially bound at working length, or at least a number 25, was deemed the master apical file. All canals were then injected with impression material and teeth cleared. Four endodontists and one general practitioner blindly evaluated the effectiveness of canal instrumentation, classifying each as excellent, satisfactory, or poor. The authors concluded that the crown-down pressureless technique received more "excellent" ratings, which was statistically significant. Both preparation techniques showed a similar incidence of zipping. However, the comparison of ledging and perforation was inconclusive as poor rater agreement led to exclusion from statistical evaluation. Thus, the authors suggest the need for more objective methods of comparison and evaluation.

The original objectives of the crown-down pressureless (step-down) techniques were to minimize the amount of periapical extrusion of debris and straightening of the root canal.[30, 163-165, 167] However, in 2005 Hulsmann[30] provided a critical review of the literature evaluating various instrumentation techniques and suggested a lack of definitive proof that the 'classical' step-down techniques are superior to step-back techniques.

In 1984 Roane and Sabala[169] microscopically examined 493 distorted or separated K-type files collected from a single practitioner. Analysis of visual observations and comparison to laboratory induced directional test fractures, revealed that counterclockwise rotation only accounted for 33.3 percent of the overall structural

separations. The authors concluded that the clinician is less likely to cause physical damage to a K-file rotated in a counterclockwise direction, which led to the development of the balanced-force technique

In 1985 Roane et al.[170] introduced the balanced-force technique to overcome the difficulties of preparing the curved root canal and to limit the risk of procedural accidents. The authors suggested that unfavorable cutting characteristics observed during the preparation of curved canals are controlled by implementing force magnitude concepts, recognizing that instruments are guided by the canal walls when rotated, and understanding that files will cut in a clockwise and counterclockwise direction. The recommended technique consisted of introducing a canal to length. Clockwise rotation was applied to the file to pull the instrument into the canal in an apical direction, but limited to 180-degrees to limit dentinal engagement.[3, 170] Rotation beyond 180-degrees had previously been shown to cause instrument unwinding coronal the engaged segment, which would increase the likelihood of separation.[169] Following the clockwise rotation, or "placement load," the file was rotated counterclockwise 120-degrees or greater with apical pressure to cut and enlarge the canal. It was suggested that this "cutting phase" circumferentially enlarged the canal to the diameter of the file while forcing the instrument coronally. The flutes of the file were cleaned and repositioned and the process was repeated until reaching the desired working length.[3, 170]

In 1987 Southard et al.[171] examined the tendency for file transportation when curved root canals were prepared with the balanced-force (Roane) technique. Standard access preparations were created and small files were progressed apically until the smallest file that bound at the level of the apical foramen was reached. Curvature of the

50 root canals were radiographically assessed and classified as unidirectional (group one) or S-curve (group two). All teeth were instrumented with the balanced-force (Roane) technique. First, a number 15 K-file was advanced in a watch-winding motion until the file tip could be visualized at the apical foramen, and the file was loose and easily retracted from the canal. Then, a straight number 20 K-file was rotated clockwise between 90 and 180-degrees depending on the relative amount of rotational resistance. Apical pressure was then applied, and the file was rotated 360-degrees counterclockwise. The file was rotated clockwise as it was withdrawn from the canal, and a number 15 K-file was used to apically clear the canal. This process was completed with progressively larger files until a number 35 file reached the established working length, apically clearing with a size number 20 K-file. Gates Glidden drills were then used to flare the coronal two-thirds of the all root canals. Apical clearing was again performed with a number 20 K-file and the balanced-force (Roane) technique was continued with successively larger files until working length was established. After each successive file transition, multiple radiographs were acquired with the adjunct of a Plexiglas jig, acrylic tooth mount, and radiographic markers to facilitate alignment and comparison of projected images. Drawings were created from the projection of radiographs and were independently evaluated. The radiographs and drawings allowed for the position of instruments from file number 20 to 45 to be compared to the original position of a number 10 or 15 file within the canal. The original position was maintained by a number 45 file in approximately 40 percent of root canals. However, the number 40 file maintained the original position 80 percent of the time. The number 25 file in the

unidirectional-curved canal was the largest file to maintain the original position in 100 percent of cases.

The major advantages of the balanced-force technique includes enhanced apical control of the file tip, excellent canal centering ability of the instrument, and no need for pre-curving the file.[1, 30] In 2005 Hulsmann critically analyzed the literature, and concluded that the balanced force technique is the only step-down technique that results in less straightening of the root canal as compared to standardized or step-back techniques.

In 1988 Walia et al.[149] compared the bending and torsional properties of traditional stainless steel K-files to that of K-type files fabricated from nickel-titanium (Nitinol) wire blanks, previously only used in orthodontics. Both files types were evaluated during cantilever bending, clockwise torsion, and counterclockwise torsion. A torque meter was used to measure values of bending and torsional moment required for file separation. Scanning electron microscopic (SEM) photographs were obtained to compare the original manufactured surface morphology of the files compared to that after torsional failure. The results showed that the Nitinol files exhibited two to three times the elastic flexibility of the stainless steel files with enhanced fracture resistance both in clockwise and counterclockwise torsion. The author's conclusions led to a surge in the development of nickel-titanium files, and initiated a paradigm shift towards rotary instrumentation of the root canal system.

In 1996 Gambill et al.[172] used computed tomography to compare nickel-titanium (NiTi) handfiles to stainless steel files using filing and reaming instrumentation techniques. Prior to instrumentation, 36 single-rooted teeth of similar shape and canal

size were scanned by computed tomography. The teeth were then allocated to one of three groups. Teeth of the first group were instrumented with K-flex stainless steel files using a quarter turn/pull technique. In the second group, teeth were also instrumented with the turn/pull technique but using Nitti hand files instead of K-flex hand files. Teeth of the third group were instrumented with the same type of Nitti hand files as group two, but with a reaming technique. All instrumentation in all groups was timed to determine overall duration of canal preparation. All instrumented teeth then were scanned with computed tomography using a plastic mounting container to insure the same orientation as pre-instrumentation images. Computer-assisted image analysis was performed to evaluate changes in canal curvature and shape, canal transportation, mean centering ratio, and volume of dentin removed. The preparation time of teeth from all three groups was also compared. The teeth in which Ni-Ti instruments were used in a reaming technique (group three) showed significantly less canal transportation, removed significantly less volume of dentin, produced significantly more centered and rounder canal preparations, and required significantly less instrumentation time than the K-flex stainless steel files using the quarter turn/pull technique (group one).

In 1997 Short et al.[173] compared canal transportation of teeth instrumented with three engine-driven Nitti instrument systems to teeth instrumented with hand files. Musial roots of 30 mandible molars were chosen and paired based on similar curvature and morphology. Various mounting jigs were used to position roots in order to maintain consistent orientation throughout experimentation. Roots were sectioned longitudinally into medial and distal halves, and horizontally at one mm, three mm, and five mm from the working length. Pre-instrumentations video images were acquired of the various

sections, and root sections were re-assembled in mounting jigs. Fifteen root canals were randomly assigned to four instrumentation groups. Root canals of the first group were instrumented with stainless steel Flex-R files using the step-back technique. The Maxim Series of Nitti rotary files were used to instrument root canals of group two. Root canals of group three were instrumented with the Light speed Nitti rotary system. The Profile 0.04 Taper Series 29 Nitti rotary instruments were used to instrument root canals of group four. Roots were disassembled after incrementing to a size of #30 and #40, and images of the sections were acquired. Total preparation time was recorded. Pre-instrumentation images were compared to post-instrumentation images using computer-assisted analysis. Centering ability of the Nitti systems proved superior to stainless steel hand files, but there was no significant difference among Nitti systems. When increasing from size #30 to size #40, the distinction between hand filing and the Nitti rotary techniques was more prominent. Root canals were prepared in significantly less time with the Nitti systems as compared to hand-filing.

Multiple nickel-titanium (Nitti) rotary instrument systems have been introduced into endodontic practice since their conception in the early 1990s. In addition to their enhanced metallurgic qualities, their rotation in the root canal produces an "Archimedes screw" effect, which transports debris from the apical to coronal direction for evacuation.[1, 23] These instrument systems are defined by their variation in design characteristics, such as taper, cross section, helix angle, pitch, and tip size.

The Prosper Universal Rotary Instruments were designed by Dr. Cliff Riddle, Dr. John West, and Dr. Pierre Macho and are marketed by DENTSPLY-Tulsa in Tulsa, Oklahoma.[1] According to Ruddle[174] the unique feature of the file revolves around its

variation in taper over the long axis of the cutting blades. The rate of coronal taper increases in the three shaping files but decreases in the five finishing files. The shaping files (S1 and S2) possess partially active tips and are used in a brushing motion to shape the coronal two-thirds of the root canal system. The S1 is 0.185 mm in diameter at the tip and 1.2 mm in diameter at D_{14}. The S2 is 0.2 mm at the tip and 1.1 mm at D_{14}. The finishing files (F1, F2, F3, F4, and F5) possess non-cutting tips, and are used in an in-out motion to prepare the apical one third of root canals. The tip diameter of the F1, F2, F3, F4, and F5 are 0.2, 0.25, 0.3, 0.4, and 0.5 mm. The Prosper file resembles a modified K-type file in cross-section. The sharp, triangular cutting edges and absence of radial lands greatly enhances cutting efficiency and flexibility. The variable helical angle and pitch over its cutting blades also balances the instrument, preventing it from screwing into the canal.[1, 174-178]

The profound popularity of the Prosper system among general dentists and endodontists alike surrounds its efficiency, simplicity, and low number of instruments required.[174-179] In fact, Ruddle[174] stated that the, "…sequence is always the same regardless of tooth or anatomical configuration of the canal being treated." Efficiency and simplicity do not come without possible consequence. In 2003, Yun and Kim[180] compared the root canal shaping abilities of the ProTaper system to that of the GT rotary, ProFile, and Quantec instruments. Simulated curved canals in plastic blocks were instrumented to size #30 using the crown-down technique. The changes in canal dimension and curvature, canal deviation, instrument deformation, and total instrumentation time were recorded and evaluated. The ProTaper system created acceptable shapes in significantly less time than the other file systems tested. However,

the overall canal curvature was significantly decreased and instrument deformation was significantly increased as compared to the other file systems. The ProTaper instruments also removed significantly more canal wall, specifically at the inner curve of the root canal. The furcal aggressiveness of the ProTaper system in the coronal aspect of root canals was also supported by Bergmans et al.[181] in 2003 and Calberson et al. [182] in 2004. The same advantageous characteristics that make the ProTaper system simple, fast, and efficient may also suggest restricted use to root canals exhibiting minimal curvature.

Although significant variability exists in instrument design of the plethora of nickel-titanium file systems available, all instruments utilize fundamental instrumentation techniques and rely on basic principles of debridement. Instruments must physically contact root canal walls to facilitate adequate debridement.[1, 30, 146] Larger preparation sizes, specifically in the apical extent of the canal, have been shown to increase cleanliness and facilitate more adequate removal of debris and microorganisms.[27-29] Apical instrumentation less than a size #30 or #35 file has also been shown to prevent irrigation solution from reaching the apical portion of the canal.[3, 183-185]

In 2002 Card et al.[29] evaluated the effect of apical instrumentation size on the amount of cultural bacteria from the canal. The mandibular cuspids, bicuspids, and molars from patients exhibiting clinical and radiographic evidence of apical periodontitis were selected for the study. Canal preparations were initially performed with the 0.04 taper ProFile series 29 nickel titanium rotary file system. The canines and premolars were instrumented to a size of 0.465 mm and the molars canals to a size of 0.599 mm. Bacterial sampling took place upon access and instrumentation. The canals were then further instrumented with the Lightspeed nickel-titanium rotary file system to a size of

0.80 mm in the canines and premolars and 0.60 in the molars. All canals were again sampled for culturable bacteria. The results showed 100 percent of canines and premolars and 81.5 percent of molar canals were free of bacteria after the first instrumentation. After the second instrumentation, 89 percent of the molars were bacteria-free. The molar mesial canals not displaying clinically detectable communication were rendered bacteria-free in 93 percent of cases after the first instrumentation.

In 2002 Rollison et al.[27] also examined the efficacy of bacterial removal from instrumented root canals of varying apical sizes, but utilized an in-vitro study model. The mesiobuccal canals of 50, extracted, mandibular molars were inoculated with a standardized quantity of radioactively labeled *Enterococcus faecalis* (E.faecalis). Baseline levels of radioactivity were obtained by washing out the unbound bacteria with buffer. Samples from group one were instrumented with Greater Taper (GT) and Profile nickel titanium rotary files to apical size of #35 and samples from group two were instrumented with Pow-R nickel-titanium rotary files to apical size of #50. Phosphate-buffered saline solution was utilized during instrumentation. Absorbent points were used to acquire the medium from each root canal after instrumentation was completed. Liquid scintillation spectrometry was utilized to quantify the radioactivity within each of the instrumented root canals. The results showed a significant increase in amount of radioactivity of samples from group two as compared to group one. The authors suggested using instrumentation to an apical size of #50 than to an apical size of #35 when debriding infected root canals.

In 2004 Usman et al.[28] compared the efficacy of root canal debridement with varying levels of apical enlargement. Greater Taper (GT) nickel-titanium rotary files were used to prepare 32 root canals of 20 matched, human cadaver teeth. Teeth on the right side of the arch were instrumented to a size of 20, while teeth on the left were instrumented to a size of 40. Irrigation was performed with a 27-gauge endodontic irrigation needle, alternating between ethylenediaminetetraacetic acid (EDTA) and 5.25-percent sodium hypochlorite. The initial depth of irrigation needle penetration, number of recapitulations required to reach instrumentation goal, volume of irrigation solution used, and final depth of irrigation needle penetration were recorded. Teeth were then extracted, fixed, demineralized, and sectioned at 0.5 mm, 1.0 mm, and 2.5 mm from the apex. Photographs of the sections were acquired under X100 magnification and amount of residual debris was calculated by computer analysis. Results showed that when all levels were combined the size 20 group left significantly more debris in the apical third when compared to the size 40 group. The 27-gauge irrigation needle was able to approximate the working length in 76.6 percent of root canals of the size #20 group, and in 94.4 percent of root canals of the size 40 group. The volume of irrigation solution and number of instrumented changes did not have a statistical contribution to efficacy of debridement. Also, the increased depth of irrigation syringe in the size 40 group did not statistically contribute to the enhanced debridement efficacy.

In 2005 Baugh and Wallace[186] performed a Medline-based review of the literature to determine the role of apical instrumentation in root canal treatment. The authors found longitudinal studies indicating that instrumentation to larger files does not statistically improve clinical outcome of root canal therapy. However, these studies were often

retrospective or possessed other limiting factors, such as sample size, that question the validity of result interpretation. More importantly, the relationship between significant enlargement of the canal space or enlargement of the apical region of the canal and clinical success were not evaluated. The authors of the review did indicate finding more specific studies to support larger apical preparations in the reduction of bacterial count and in enhancement of canal cleanliness. They also concluded that instrumentation to larger apical sizes enhances removal of microbes and allows for more efficacious irrigation of the root canal system. The authors also provide scientific evidence showing an obvious relationship between high success rate and proper cleaning prior to obturation. Using a review of anatomic studies, they showed that the apical constriction and three to four mm coronal may be larger than the apical size advocated by some instrument manufacturers. The authors overall conclusion included a recommendation to seek instruments and techniques that effectively determine the point in which correct apical instrumentation has been established dependent on the various apical dimensions of root canals.

Due to anatomic variations, it may not always be possible to enlarge root canals to an ideal diameter during instrumentation. Also, the larger the canal preparation, the greater amount of dentin is removed from the canal walls, which can lead to a weakened root.[187] Even with enlargement of the canal space, mechanical debridement cannot completely sterilize the canal.[23] Manual and rotary instruments are inefficient in completely debriding the canal largely due to their inability to contact all aspects of the canal wall.[23-26] This is due to the presence of multiple morphologic factors including lateral and accessory canals, canal curvatures, canal wall irregularities, fins, cul-de-sacs,

isthmuses, and highly variable root anatomy.[3, 27-30] Even if all canal walls are accessed and mechanically planed, bacteria may remain viable within the dentinal tubules of the root canal wall.[188]

In 2005 Hulsmann et al.[30] examined goals, techniques, and means of mechanical preparation of the root canal system. The main flaws in the literature regarding root canal preparations were exposed and endodontic instrumentation and techniques were critically reviewed. It was suggested that the literature is plagued with various methodological problems and largely based on limited clinical and scientific evidence. However, the authors arrived at the following conclusions:

1) Nickel-titanium (Ni-Ti) instruments assist in the preparation of the root canal system, especially curved canals.
2) Each root canal system will dictate the preparation technique and final preparation size.
3) Although bacterial load may be reduced from mechanical preparation, root canals will not reproducibly be left bacteria-free.
4) Mechanical preparation of the root canal must be accompanied by appropriate irrigation solutions and intracanal medications implementing intense disinfection methods.
5) If copious volumes of the appropriate irrigation solutions are not implemented, mechanical preparation will leave residual debris and smear layer along the root canal wall.

IRRIGATION SOLUTIONS

In order to further eradicate microorganisms from the root canal system, irrigation solutions are recommended as an adjunct to mechanical preparation of the root canal system in a process called chemomechanical debridement.[1, 3, 31, 34, 189, 190] Irrigation allows pathogens present in dentinal tubules, crevices, fins, and isthmuses to be accessed, destroyed, and flushed from root canal system.[1, 2, 32, 33] In fact, even when saline was used as an irrigation solution during mechanical instrumentation, a ten-fold to a thousand-fold decrease in bacterial load has been observed.[1, 23, 26] Irrigation solutions can also aid in the prevention of hard and soft tissue from being packed apically or into the periapical tissues.[2]

An ideal irrigation solution should dissolve organic and inorganic tissue, differentiate between necrotic and vital host tissue, lubricate the canal, prevent and remove the smear layer, exhibit low surface tension, provide broad-spectrum antimicrobial action, retain its effectiveness with dental hard tissue and when mixed with other irrigation solutions, and inactivate endotoxin while remaining locally and systemically nontoxic to normal host tissues with little potential to cause an anaphylactic reaction.[1-3, 191-194] Unfortunately, no solution meets all of these requirements.[1-3] Therefore, a combination of solutions is often used in an irrigation regimen to utilize advantageous qualities of each irrigation solution separately.[34, 35] Although many solutions have been suggested the irrigation solutions most commonly used in modern nonsurgical endodontic therapy are sodium hypochlorite, chlorohexidine, and ethylenediaminetetraacetic acid (EDTA).[1-3] Each solution provides its own set of

advantages and disadvantages, but at certain concentrations all of these solutions are inhibited or even inactivated by contact with dentin or dentin powder.[195, 196]

Sodium Hypochlorite

Sodium hypochlorite (NaOCl) is the most commonly used irrigation solution in endodontics.[1-3] Its profound popularity revolves around its antimicrobial activity, property to dissolve vital and necrotic tissue, lubricating action, low cost, and availability.[1, 3, 25, 197-199] The effectiveness of sodium hypochlorite is limited by its requirement for direct contact and inability to adequately access all areas of the canal, specifically the most apical extent of preparation.[1, 2] Since irrigation of the canal is limited to approximately one mm beyond the irrigation tip, smaller gauge needles have been recommended.[183, 200-202] However, smaller irrigating needles may promote extrusion of sodium hypochlorite via apical foramen especially if needle binds[203] or in a case where an open apex exists.[204] Sodium hypochlorite is very cytotoxic to host cells and extrusion beyond the apex could lead to a "sodium hypochlorite accident" resulting in toxicity to host cells and/or serious detrimental health effects.[205-212] Even if sodium hypochlorite is able to reach all aspects of the root canal system without being apically extruded its ability to remove dentin or smear layer is minimal.[34, 200] Lastly, sodium hypochlorite possesses an unpleasant taste.[1-3]

Sodium hypochlorite first emerged in the treatment of root canals and periapical infections in the form of Dakin's solution, near the end of World War I. Dakin's solution was originally used for wound debridement on the battlefield. This 0.5-percent solution of sodium hypochlorite was later implemented into the root canal cleaning regimen.[85, 108] Dakin's solution and some 1.0-percent sodium hypochlorite solutions are buffered with

sodium bicarbonate buffer decreasing the pH from 11 (unbuffered) to nine.[213-215] Lowering the pH made the solution less toxic to the vital tissues being debrided.[108] The more commonly used unbuffered solutions range in concentration from 0.5 percent to 7.0 percent and include household bleach (6.0 percent).[216] The concentration and pH of sodium hypochlorite affect its tissue dissolution and antimicrobial properties.[213-215, 217]

When reacting with water, sodium hypochlorite ionizes to produce Na^+ and the hypochlorite ion (OCl^-), which establishes equilibrium with hypochlorous acid (HOCl). When pH is above nine, the hypochlorite ion (OCl^-) predominates, but when the pH is between four and seven hypochlorous acid (HOCl) predominates. The hypochlorite ion (OCl^-) provides available free chlorine used to dissolve necrotic tissue and organic debris by breaking down proteins into amino acids.[213-217] This free chlorine is depleted during the tissue dissolution requiring frequent replenishment of sodium hypochlorite especially when lower concentrations are utilized or small, narrow canals are irrigated.[1] The hypochlorous acid (HOCl) plays a more significant role in the inactivation of bacteria by disrupting oxidative phosphorylation and DNA synthesis.[216] Therefore, the tissue dissolution effect of sodium hypochlorite is enhanced as the pH is increased, but at the expense of its antimicrobial action. [213-217] Decreasing the pH with bicarbonate lead to instability of sodium hypochlorite, which reduces its shelf life to less than one week.[218] Increasing the concentration of sodium hypochlorite will result in a relative increase in tissue dissolution and antimicrobial effect compared to a lower concentration at the same pH.[213-217] However, increasing the concentration also increases the relative cytotoxicity of solution, which can worsen the negative sequelae of a "sodium hypochlorite accident."[205, 219]

In 1971, Shi et al.[220] designed an in-vitro study involving two experiments to investigate the bactericidal efficiency of sodium hypochlorite as a root canal irrigation solution. The first experiment utilized serial tube dilutions to examine the germicidal efficiency of 5.25-percent sodium hypochlorite. A standardized volume of full-strength 5.25-percent (pH =11 to 11.5), 0.525-percent (1:10), 0.0525-percent (1:100), 0.00525-percent (1:1000), or 0.000525-percent (1:10,000) were added to two sets of six test tubes. Bacto-ascitic fluid from cultures of *Streptococcus faecalis* and *Staphylococcus aureus* were added each of the sets of six test tubes. The tubes were agitated during experimentation, samples were cultured from inoculated salutations at 30 seconds, one, two, three, four, five, ten, and 20 minutes, and 24 hours. After incubation under aerobic conditions, the *Streptococcus faecalis* and *Staphylococcus aureus* were completely eradicated in 30 seconds when added to 5.25-percent (pH =11 to 11.5), 0.525-percent (1:10), 0.0525-percent (1:100), and 0.00525-percent (1:1000) sodium hypochlorite. However, the 0.000525-percent (1:10,000) sodium hypochlorite did not inhibit bacterial growth, even after 24 hours of contact. The second experiment examined the germicidal efficiency of 5.25-percent sodium hypochlorite as a root canal irrigation solution. Standard endodontic preparations were performed on 120 extracted teeth. After the teeth were sterilized, 60 were inoculated with *Streptococcus faecalis* and 60 were inoculated with *Staphylococcus aureues*. Pre-irrigation culture samples were acquired from the inoculated root canals. Roots root canals were then irrigated with standardized volumes of 5.25-percent (pH =11 to 11.5) or 0.525-percent (1:10) sodium hypochlorite. A disposable syringe with 25-gauge needle was used for irrigation. A post-irrigation culture was acquired, and all samples were again incubated under anaerobic conditions.

Cultures were then acquired at two and seven days. Full-strength, 5.25-percent sodium hypochlorite eradicated all cultivatable bacteria immediately, but provided positive cultures at two and seven day periods. The 0.525-percent (1:10) sodium hypochlorite did not eradicate all bacteria immediately and also provided positive cultures at two and seven day periods. The amount of cultivatable bacteria was higher at seven days than at two days in both groups. When sterile distilled water was used as a control, 18 or 19 of the 20 teeth exhibited growth of either microorganism in all test periods. The authors concluded that the sodium hypochlorite bactericidal effect observed in tube dilution studies cannot be expected in extracted human teeth. They also indicated the necessity of full-strength, 5.25-percent sodium hypochlorite to eradicate viable bacteria, but warned that it will not provide a lasting effect.

In 1971 Senia[221] evaluated the solvent action of 5.25-percent sodium hypochlorite on pulp tissue from the root canals of extracted, mandibular molars to determine the solvent action. Standard root canal preparation techniques were implemented on the two canals of the mesial root. Full-strength, 5.25-percent sodium hypochlorite was used as an irrigation solution in one canal while normal saline solution was used as a control in the other canal. Irrigation took place for time intervals of 15 and 30 minutes. Roots were cross-sectioned at one, three, and five mm levels from the apices. The sections were then stained, and examined at X100 magnification via light microscopy. An evaluation was performed of the root canal contents and any isthmus present between the two canals. The author arrived at the following conclusions:

1) Full-strength, 5.25-percent sodium hypochlorite generally provided more efficacious dissolution of human pulp tissue, but there was no significant

difference in cleaning effect at the one and three mm levels. Full-strength, 5.25-percent sodium hypochlorite provided significantly cleaner canals than saline solution at the five mm level.

2) Full-strength, 5.25-percent sodium hypochlorite provided significantly enhanced pulp tissue dissolution within isthmuses at the one, three, and five mm levels.
3) Full-strength, 5.25-percent sodium hypochlorite was less effective in small, apical constrictions as compared to the larger diameters of the root canal system.
4) Standard endodontic techniques did not provide adequate debridement of the apical five mm of the root canal.
5) The pulp tissue dissolution quality of sodium hypochlorite is questionable in the apical three mm of the root canal system.

A few years later in a similar study, Rosenfeld et al.[198] evaluated the solvent action of 5.25-percent sodium hypochlorite on vital human pulp tissue. The authors also sought to determine the effect of sodium hypochlorite on the canal walls, residual tissue, accessory canals, and apical pulp stump of instrumented roots. Forty-two, non- carious, unrestored premolars from young orthodontic patients were placed into two groups. The twenty teeth of the first group were accessed clinically under rubber dam isolation, irrigating the coronal aspect of pulp tissue for 15 minutes with full-strength, 5.25-percent sodium hypochlorite. No instrumentation was performed. The teeth of the second group were instrumented with K-type files to within five mm from the apices. Irrigation was performed for 15 minutes with full-strength, 5.25-percent sodium hypochlorite or normal

saline solution. Teeth were extracted, decalcified, embedded, sectioned, stained with hematoxylin and eosin or Masson's trichrome connective tissue stain, and examined with a light microscope. Two independent, blinded examiners evaluated the specimens. The results indicated that full-strength; 5.25-percent sodium hypochlorite exerted an enhanced, non-specific, surface-acting, solvent action on vital pulp tissue that was significantly superior to that of normal saline solution. The red blood cells and presenting were most readily altered. Unfortunately, a small root canal lumen limited the solvent action of sodium hypochlorite, which was most effective in the coronal and middle thirds of the root canal system.

In 1977, Trepagnier et al.[222] examined the tissue dissolution of sodium hypochlorite in endodontically treated root canals when the concentration and reaction times were altered. The root canals of 140, single-rooted, human teeth containing vital pulp tissue were divided into seven groups. The first four groups were irrigated with 5.25-percent sodium hypochlorite for one, five, 15, and 60 minutes. The fifth group was irrigated with 2.5-percent sodium hypochlorite for five minutes, and the sixth group was irrigated with Dakin's solution (0.5-percent sodium hypochlorite at pH of 9) for five minutes. The seventh group was irrigated with normal saline for 15 minutes. The amount of hydroxyproline content of the irrigation solution after irrigation was measured to determine the amount of dissolved collagen-containing tissue. The results indicated that sodium hypochlorite provides powerful tissue dissolution immediately upon contact that continued for at least 60 minutes. Half of the collagen dissolved over 60 minutes was dissolved in the first 60 seconds of the reaction, and significantly decreased in rate after five minutes. Although there were no statistically significant differences between

the full and half-strength concentrations of sodium hypochlorite, the full-strength was significantly more effective than Dakin's solution. The normal saline solution provided no tissue dissolution quality.

In 1978 Hand et al.[223] compared various concentrations of sodium hypochlorite, 3.0-percent hydrogen peroxide, normal saline, and distilled water to evaluate differences in necrotic tissue dissolution properties. Standardized amounts of necrotic connective tissue of rat pelts were exposed to standardized volumes of 5.25-percent sodium hypochlorite, 2.5-percent sodium hypochlorite, 1.0-percent sodium hypochlorite, 0.5-percent sodium hypochlorite, 3.0-percent hydrogen peroxide, normal saline, and distilled water for a standardized time interval. The mean percentage of weight change for each specimen exposed to test solution was calculated and statistically analyzed. The results indicated significantly superior necrotic tissue solvent properties of 5.25-percent sodium hypochlorite as compared to 2.5-percent sodium hypochlorite, 1.0-percent sodium hypochlorite, 0.5-percent sodium hypochlorite, 3.0-percent hydrogen peroxide, normal saline and distilled water. The necrotic tissue dissolution property is significantly decreased when diluting 5.25-percent sodium hypochlorite. All solutions tested, except 5.25-percent sodium hypochlorite, were ineffective in their ability to dissolve necrotic tissue. Although 2.5-percent sodium hypochlorite was significantly more effective as a necrotic solvent than 1.0-percent or 0.5-percent sodium hypochlorite, there was no significant difference between 1.0-percent and 0.5-percent sodium hypochlorite.

In 1981 Gordon et al.[224] performed a similar study to compare the vital and necrotic tissue dissolution effects of various concentrations of sodium hypochlorite. Standardized amounts of bovine pulp tissue were exposed to standardized volumes of

distilled water, 1.0-percent, 3.0-percent, and 5.0-percent solutions of sodium hypochlorite for two, five, and 10 minutes. Pre-experimentation tissue weights were compared to tissue weights at different time intervals to determine the percentage of vital and necrotic tissue dissolved by each solution. Distilled water exhibited virtually no dissolution of vital tissue, with less than a 10-percent weight loss in 10 minutes. However, approximately 30 percent of necrotic tissue was dissolved by distilled water over 10 minutes. Approximately 37 percent of vital tissue exposed to 1.0-percent sodium hypochlorite was dissolved over two minutes. Longer exposure periods did not significantly increase tissue dissolution. Approximately 70 percent of vital tissue exposed to 3.0-percent and 5.0-percent solutions of sodium hypochlorite was dissolved in two minutes, with no increase in tissue dissolution with extended periods of time. The vital tissue was more readily dissolved with 75-percent dissolution observed in 1.0-percent, 3.0-percent, and 5.0-percent sodium hypochlorite over two minutes. Approximately 85 percent of necrotic tissue was dissolved in five minutes by these same solutions. There was no significant difference among 1.0-percent, 3.0-percent, and 5.0-percent solutions of sodium hypochlorite in their dissolution of necrotic tissue, nor was there an increase in dissolution efficacy between five and 10 minutes. The last portion of the study showed that a decrease in vital tissue solvent action of 5.0-percent sodium hypochlorite when exposed to increasing amounts of vital tissue. Seemingly, this was a result of inability of sodium hypochlorite to adequately wet the entire surface area of vital pulp tissue.

In 1982 Moorer and Wesselink[213] described some of the effects of concentration, pH, fluid flow, and surface area of tissue on the solvent properties of sodium

hypochlorite. The first portion of the experiment included exposure of various concentrations of protein hydrosylate to 3.0-percent, 1.5-percent, and 0.6-percent sodium hypochlorite. The second portion of the experiment involved exposing various weights of necrotic rabbit liver to the previously mentioned concentrations of sodium hypochlorite. The results of the first experiment indicated that the protein hydrosylate was being dissolved by the sodium hypochlorite was also responsible for simultaneous inactivation of the sodium hypochlorite. Most of the active chlorine was lost within the first two minutes of mixing. When sodium hypochlorite existed in excess volume, only a small percentage of activity was lost. However, large amounts of organic material quickly exhausted the activity of sodium hypochlorite and dramatically decreased the pH within moments of initiating the reaction. The results of the second portion of the experiment revealed that increasing amounts of organic material exposed to sodium hypochlorite, decreasing initial pH of sodium hypochlorite, and/or decreasing the concentration of sodium hypochlorite significantly reduced the time span needed to deplete half of the original concentration of active chlorine. The authors concluded that the solvent action of sodium hypochlorite decreases with increasing amount of organic material exposed. The frequency and intensity of mechanical agitation (fluid flow) increases the tissue dissolution property of sodium hypochlorite. Increased surface area of free or enclosed tissue also increases the solvent effects of sodium hypochlorite. Since large volumes of sodium hypochlorite, mechanical agitation, and fluid replenishment seemed to be the most important factors in maximizing tissue dissolution effect of sodium hypochlorite, the authors recommended concentrations between 0.5 percent and 2.0 percent.

In 1992 Baumgartner and Cuenin[225] used scanning electron microscopy (SEM) to examine the debridement efficacy of various concentrations of sodium hypochlorite on the middle third of root canals. An endodontic needle or ultrasonic device was used in the delivery of 5.25-percent, 2.5-percent, 1.0-percent, or 0.5-percent sodium hypochlorite to the root canals of extracted, matched pairs of single-rooted premolars. Loose debris from was effectively removed from root canals with all concentrations of sodium hypochlorite, but smear layer with some exposed dentinal tubules was observed on all instrumented surfaces. Pulpal remnants and predentin were completely removed from the uninstrumented surfaces from root canals exposed to 5.25-percent, 2.5-percent, and 1.0-percent sodium hypochlorite. However, the root canals irrigated with 0.5-percent sodium hypochlorite revealed some residual fibrils on the uninstrumented surfaces.

In 2008 Christensen et al.[215] altered the pH of sodium hypochlorite to determine effect on its tissue-dissolution property. Porcine tissue was exposed to normal saline and sodium hypochlorite of various concentrations and pH for five, 15, and 30 minutes. Group one was exposed to saline, group two to 5.25-percent sodium hypochlorite at pH 12, group three to 2.6-percent sodium hypochlorite at pH 12, group four to 5.25-percent sodium hypochlorite at pH of nine, group five at 2.6-percent sodium hypochlorite at pH of 9, group six to 5.25-percent sodium hypochlorite at pH of six, and group seven to 2.6-percent sodium hypochlorite at pH of six. Tissue was weighed prior to and after exposure to the different solutions. The results indicated that the tissue dissolution of property of sodium hypochlorite is significantly greater with full strength (5.25 percent) compared to half-strength (2.6 percent) at the same pH when pH ranged between nine and 12. However, no significant difference was seen between 5.25-percent and 2.6-

percent sodium hypochlorite when pH was titrated to 6.0. Increased exposure time of tissue to sodium hypochlorite increases its percentage of dissolution. When the pH remained unadjusted at twelve, the percentage of tissue dissolution between each time interval was significant. However, decreasing the pH significantly decreased the percentage of tissue dissolution over a given time period. The authors concluded that higher concentration, increased pH, and increased exposure of sodium hypochlorite equated to greater tissue dissolution. However, the authors also stated that although lowering the pH of sodium hypochlorite will increase tissue dissolution, it will also decrease its antimicrobial effect.

In addition to the tissue-dissolution properties of sodium hypochlorite, its antimicrobial effects have also been extensively studied. In 1976, Cvek et al.[226] compared the antibacterial effects of chemomechanical debridement of non-vital immature and mature maxillary incisors. Clinically, teeth were mechanically instrumented with the adjunct of sterile saline or sodium hypochlorite. Root canals of group one were irrigated with sterile saline solution, group two with 0.5-percent sodium hypochlorite, and group three with 5.0-percent sodium hypochlorite. Bacteriologic samples were acquired prior immediately following removal of necrotic tissue and again following completion of disinfection. Samples were cultured for ten days under aerobic and anaerobic conditions, and microorganisms were identified by biochemical tests and gas-chromatographic analysis. The results revealed that the antibacterial effect of mechanical debridement and normal saline was 9.0 percent and limited to mature teeth. The antibacterial effect of mechanical debridement and sodium hypochlorite was 25 percent and significantly greater than that of normal saline. There was no significant

difference in antibacterial effect between the 5.0 percent and 0.5 percent concentrations of sodium hypochlorite in immature teeth. However, when immature teeth were irrigated, the antibacterial effect of both concentrations of sodium hypochlorite was reduced with no significant differences between concentrations. The authors concluded that the disinfection of immature roots with available instruments and sodium hypochlorite is ineffective and unable to be compensated by increasing concentration.

In 1981 Harrison[227] examined the antibacterial effect of sodium hypochlorite after dilution and/or exposure to organic material. Absorbent points contaminated with *Streptococcus faecalis* were exposed to sodium hypochlorite in concentrations of 5.25-percent, 2.5-percent, 1.0-percent, 0.5-percent, hydrogen peroxide in concentration of 3.0-percent, 3.0-percent hydrogen peroxide and 5.25-percent sodium hypochlorite, and normal saline solution. A second experiment consisted of addition of organic material consisting of yeast extract, whole blood, or human serum albumin to test tubes consisting of *Streptococcus faecalis* contaminated paper points and 5.25-percent sodium hypochlorite. The absorbent points were exposed to solutions for five seconds, ten seconds, 30 seconds, 45 seconds, 60 seconds, 90 seconds, two minutes, five minutes, and 15 minutes. Cultures were incubated and subcultured. The results revealed that 5.25-percent sodium hypochlorite was most effective of tested solutions against *Streptococcus faecalis.* The antibacterial property of sodium hypochlorite was significantly reduced after dilution. Normal saline solution and the combination of 3.0-percent hydrogen peroxide and 5.25-percent sodium hypochlorite exhibited no antibacterial effects against *Streptococcus faecalis.* The antibacterial property of 5.25-percent sodium hypochlorite

was not affected by whole blood or serum albumin but was significantly inhibited by the presence of yeast extract.

In 1983, Bystrom and Sundqvist[189] compared the amount and species of bacteria remaining in root canals prior to and after instrumentation with the adjunct of normal or 0.5-percent sodium hypochlorite. Necrosis of thirty, single-rooted teeth was confirmed by clinical signs and symptoms as well as radiographic evidence of bone destruction. In the first group of fifteen teeth, normal saline solution was used, and in the other fifteen teeth, 0.5-percent sodium hypochlorite was used. Each tooth was instrumented and irrigated at five appointments, with bacterial samples acquired via absorbent paper points at the beginning and end of each appointment. All samples were cultured under aerobic and anaerobic conditions. Antibacterial dressing was not utilized in between appointments. The results indicated that anaerobic bacteria dominate the root canal system. The numbers of bacterial cells depended on the concentration of cells originally cultured from the root canal. The amount of residual bacteria at the fifth appointment was significantly decreased in the root canals irrigated with 0.5-percent sodium hypochlorite as compared to those irrigated with normal saline solution.

In 2000 Siqueira et al.[228] compared the reduction in bacteria load of root canals instrumented and irrigated with normal saline, 1.0-percent, 2.5-percent, and 5.25-percent sodium hypochlorite solutions. Forty, extracted, single-rooted, mandibular premolars were initially instrumented and irrigated with tap water. Teeth were mounted in plaster blocks and sterilized by ethylene oxide gas. Standardized amounts of *Enterococcus faecalis* were then introduced into the root canal systems with tuberculin syringes and a sterile K-type file. The teeth were then divided into four groups dependent on irrigation

solution utilized during instrumentation. The first group was irrigated with 1.0-percent sodium hypochlorite, the second group with 2.5-percent sodium hypochlorite, the third group with 5.25-percent sodium hypochlorite, and the fourth group with 0.85-percent normal saline solution during instrumentation. The same volume of solution was introduced into the root canals of each group with a 23-gauge needle. Root canals were sampled prior to and following instrumentation with absorbent paper points. After incubation of the samples, colony-forming units were counted and an agar diffusion test was performed. The results indicated a significant reduction in the number of bacterial cells present in root canals irrigated with sodium hypochlorite, but no significant difference between the 1.0-percent, 2.5-percent, and 5.25-percent concentrations. Large zones of inhibition against *Enterococcus faecalis* were noted with all concentrations of sodium hypochlorite. All concentrations of sodium hypochlorite were significantly more effective than 0.85-percent normal saline solution. The authors concluded that regular and frequent exchange with large volumes of sodium hypochlorite should compensate for lower concentration, maintaining antibacterial effectiveness.

In 2002 Zehnder et al.[214] compared various concentrations of unbuffered sodium hypochlorite to various concentrations buffered at different pH levels to determine effects on antimicrobial and tissue dissolution properties. Vital and necrotic tissue from freshly dissected pig palates was exposed to unbuffered 2.5-percent sodium hypochlorite at pH of 12, unbuffered 0.5-percent sodium hypochlorite at pH of 12, buffered 0.5-percent sodium hypochlorite at pH of 12, and buffered 0.5-percent sodium hypochlorite at pH of nine. Tissue was weighed prior to and after to exposure to sodium hypochlorite with tissue dissolution expressed as a percentage of original tissue weight. Enterococcus

faecalis in dentin blocks and on filter papers was also exposed to the various sodium hypochlorite solutions to determine antimicrobial efficacy. The results indicated that 2.5-percent sodium hypochlorite was significantly more effective at dissolving tissue than all 0.5-percent sodium hypochlorite solutions. Tissue dissolution was not significantly affected by buffering of sodium hypochlorite, and Dakin's solution showed equivalent dissolution of vital and decay tissues. The antibacterial effect of Dakin's solution was not significantly superior to the equivalent concentration (0.5-percent) of unbuffered sodium hypochlorite. The authors concluded that buffering sodium hypochlorite with sodium bicarbonate did not provide any tissue dissolution or antimicrobial benefits over unbuffered sodium hypochlorite of the same concentration. They also recommended diluting sodium hypochlorite with water instead of sodium bicarbonate.

In 2006 Clegg et al.[229] evaluated the antimicrobial efficacy of 6.0-percent sodium hypochlorite, 3.0-percent sodium hypochlorite, 1.0-percent sodium hypochlorite, 2.0-percent chlorhexidine, and MTAD on polymicrobial biofilms. Ten teeth clinically diagnosed with pulpal necrosis and chronic apical periodontitis were chosen for the study. All teeth were isolated and accessed without water spray. Sterile paper points were positioned in the root canals, allowed to sit undisturbed for 60 seconds, and immediately transferred to the laboratory. Five ml samples of whole saliva were also collected from each patient. The apical five mm from seventy extracted single-rooted teeth was removed and longitudinally sectioned. The smear layer was removed by placing the sections in an ultrasonic bath with 17-percent ethylenediaminetetraacetic acid (EDTA). Specimens were then ultrasonically cleaned and sterilized by autoclave. Pellicle layer was formed on the specimens by soaking in patients' saliva for 24 hours.

The *in-vivo* bacteria samples from paper points were introduced to the pellicle of the dentin sections. A total of 140, five-mm longitudinal sections containing biofilm were immersed in different irrigation solutions. Group one was exposed to 6.0-percent sodium hypochlorite for 15 minutes; group two was exposed to 3.0-percent sodium hypochlorite for 15 minutes; group three was exposed to 1.0-percent sodium hypochlorite for 15 minutes; group four was exposed to 1.0-percent sodium hypochlorite for 15 minutes followed by MTAD for five minutes, and group five was exposed to 2.0-percent chlorhexidine for 15 minutes. One of the longitudinal halves of each section in each group were evaluated under scanning electron microscopy (SEM) to detect presence of biofilm. The second half of the longitudinal section was cultured in order to determine bacterial viability. According to SEM analysis, all solutions except 2.0-percent sodium chlorhexidine were able to disrupt the biofilm. Only 6.0-percent and 3.0-percent sodium hypochlorite were capable of removing biofilm. Viable bacteria could not be identified after irrigation with 6.0-percent sodium hypochlorite, 2.0-percent chlorhexidine, or 1.0-percent sodium hypochlorite and MTAD. The authors concluded that the only irrigation solution able to physically remove biofilm and render bacteria nonviable was 6.0-percent sodium hypochlorite.

One alternative approach to improving the tissue dissolution and antimicrobial efficacy of sodium hypochlorite without some of the negative effects of altering pH involves increasing the temperature of low-concentration solutions.[218] Gambarini et al.[230] showed that heated and non-heated solutions maintained free chlorine content and pH values after 30 days that preserved the outstanding tissue-dissolution and antibacterial properties of original sodium hypochlorite solution.

In 1980, Cunningham and Balekjian[231] compared the collagen-dissolving ability of 5.2-percent and 2.6-percent sodium hypochlorite at 21 degrees Celsius (room temperature) and 37 degrees Celsius (body temperature). The results indicated that the solvent action of 2.6-percent sodium hypochlorite at 37 degrees Celsius was equivalent to that of 5.2-percent sodium hypochlorite at 21 degrees Celsius or 37 degrees Celsius. The same year Cunningham and Joseph[232] also compared the bactericidal effect of 2.6-percent sodium hypochlorite at room temperature and body temperature. The results revealed that the body temperature solution was able to achieve sterility in less time than the room temperature solution.

In 2005 Sirtes et al.[233] assessed the short-term stability of preheated sodium hypochlorite solutions, compared the effects of varying temperature on the tissue dissolution effect of sodium hypochlorite, and evaluated the antibacterial efficacy of heated sodium hypochlorite solutions. The 60-minute stability of 5.25-percent, 2.62-percent, and 1.0-percent sodium hypochlorite solutions heated to 20, 40, and 60 degrees Celsius was evaluated. Human pulp tissue dissolution was assessed by comparing 1.0-percent sodium hypochlorite at 45 and 60 degrees Celsius to that of 5.25-percent sodium hypochlorite at 20 degrees Celsius. The killing efficacy of 0.001-percent, 0.0001-percent, and 0.00001-percent sodium hypochlorite at 20 °C and 45 °C against incubations of *Enterococcus faecalis* was compared. The results revealed that all solutions remained stable during all time periods. Human pulp tissue was as effectively dissolved by 1.0-percent sodium hypochlorite at 45 °C as by 5.25-percent sodium hypochlorite at 20 °C. The tissue dissolution property of 1.0-percent sodium hypochlorite at 60 °C was significantly superior to that of 5.25-percent sodium hypochlorite at 20 °C. There was a

100-fold decrease in bacterial load after exposure to equivalent concentrations of sodium hypochlorite heated to 45 °C and compared with the load at 20 °C.

Chlorhexidine

Chlorhexidine (CHX) is widely utilized as a disinfecting agent due to its broad spectrum of antimicrobial activity, effective against gram-positive and gram-negative bacteria as well as various fungi.[1-3, 33, 234, 235] In addition, its growing acceptance as an endodontic irrigation solution revolves around its exceptional substantivity and low toxicity.[208, 236-243] Some practitioners prefer chlorhexidine over sodium hypochlorite due to less irritation to periapical tissues, absence of unpleasant smell, and lack of "bleaching" of patient's clothing.[2, 244] However, unlike sodium hypochlorite, chlorhexidine is completely devoid of tissue dissolution properties.[2, 3, 245] When sodium hypochlorite and chlorhexidine are used together, tissue is adequately dissolved and a synergistic antimicrobial effect is created.[239] However, chlorhexidine and sodium hypochlorite are not soluble in one another. There combination leads to the formation of para-chloroaniline, a brownish-orange precipitate and known carcinogen.[218, 244, 246, 247] Other drawbacks of chlorhexidine include its inability to remove smear layer and reduction in efficacy in the presence of organic material.[1-3]

The antimicrobial effect of chlorhexidine is produced by binding of its cationic molecular component to the negatively charged areas of the cytoplasmic membrane of bacteria or the inner membrane of yeasts, which leads to cell lysis.[1, 2] This cationic component also binds to hydroxyapatite of tooth structure, which contributes to its substantivity and long-lasting antibacterial effect in the root canal system.[1] Chlorhexidine used in high concentration also causes coagulation of microbial

intracellular components.[217] Its activity against Gram-positive bacteria is superior to that of Gram-negative bacteria, and mycobacteria and bacterial spores exhibit resistance to chlorhexidine.[2] Most viruses are protected from the effects of chlorhexidine, with the exception of those with lipid envelopes.[248] Multiple studies have shown comparable antimicrobial effects of chlorhexidine to that of sodium hypochlorite while others have suggested that chlorhexidine is more efficacious at killing specific microbial species responsible for persistent endodontic infection.[208, 238, 240, 242, 249, 250]

In 1997 White et al.[241] evaluated the *in-vitro* antimicrobial substantivity of various concentrations of chlorhexidine in instrumented root canals. The root canals of single-rooted, human teeth were instrumented using 2.0-percent and 0.12-percent chlorhexidine irrigation solutions. The root canals were then filled with sterile water and absorbent paper points were used to sample root canal fluid at six h, 12 h, 24 h, 48 h, and 72 h after treatment. The paper points were placed on agar placed inoculated with *Streptococcus mutans.* The residual antimicrobial effect of chlorhexidine was assessed by measuring the zones of inhibition. Antimicrobial activity of 2.0-percent chlorhexidine remained throughout the 72 hours of testing. In most cases, the antimicrobial activity of 0.12-percent chlorhexidine was present between six h and 24 h after irrigation. These findings were also supported by Rosenthal et al.[237] who reported that antimicrobially effective levels of chlorhexidine were maintained in bovine root canal dentin for up to 12 weeks.

In 2003 Yamashita et al.[251] examined the *in-vitro* root canal wall debridement efficacy of instrumentation and irrigation with various irrigation solutions using scanning electron microscopy (SEM). Freshly extracted human teeth were placed in four groups of nine depending on the irrigation solution utilized. Teeth of group one were irrigated with

normal saline solution, group two with 2.0-percent chlorhexidine, group three with 2.5-percent sodium hypochlorite, and group four with 2.5-percent sodium hypochlorite followed by 17-percent ethylenediaminetetraacetic acid (EDTA). All teeth were instrumented with K-type files to the same apical diameter and implementing the step-back technique to a size 80 file. The same volume of solution was utilized during instrumentation of all groups, and distilled water was used as the final irrigation solution. The EDTA of group four was delivered to root canals after final instrumentation and was agitated for three minutes prior to rinsing with distilled water. All canals were dried with paper points. Roots were longitudinally sectioned and examined with a scanning electron microscope. Photographs were acquired at various magnifications and scored according to relative amount of residue associated with dentinal tubules. The results revealed inferior cleaning in the apical third of all root canals regardless of irrigation solution utilized. However, saline and chlorhexidine left root canal walls with more residual debris as compared to sodium hypochlorite with and without adjunct of EDTA.

In 2003 Oncag et al.[208] compared the antibacterial properties and toxicity of 5.25-percnet sodium hypochlorite, 2.0-percent chlorhexidine gluconate, and 0.2-percent chlorhexidine plus 0.2-percent cetrimide. Sixty freshly extracted single rooted human teeth were sterilized and then infected with *Enterococcus faecalis*. Each irrigation solution was used to irrigate a total of 15 teeth. The antibacterial effects of the various irrigation solutions were evaluated after five minutes and 48 hours. The 2.0-percent chlorhexidine gluconate with and without the addition of 0.2-percent cetrimide was significantly more effective at eradicating *Enterococcus faecalis* than 5.25-percent sodium hypochlorite at five minutes. There were no statistically significant differences

between groups at 48 hours. Bacterial culture samples were also collected *in-vivo* from ninety-one infected root canals of deciduous teeth with necrotic pulps. The root canals were irrigated with the different irrigations solutions and left empty for 48 hours. Samples were acquired and cultured allowing determination in differences in aerobic, facultative anaerobic, and anaerobic bacterial growth in the different irrigation groups. The results revealed that 2.0-percent chlorhexidine with or without the addition of 0.2-percent cetrimide was significantly more effective at eradicating anaerobic bacteria than 5.25-percent sodium hypochlorite. The final aspect of the study consisted of injected the various irrigation solutions into the subcutaneous tissues of rats and histologically evaluating the tissues after two weeks. The results revealed that 5.25-percent sodium hypochlorite exhibited significantly more cytotoxicity than 2.0-percent sodium hypochlorite with or without 0.2-percent cetrimide. The authors concluded that 2.0-percent chlorhexidine with or without the addition of 0.2-percent cetrimide exhibited more antibacterial efficacy with greater antibacterial substantivity and less cytotoxicity compare to 5.25-percent sodium hypochlorite.

In 2003 Zamany aspired to determine if the addition of 2.0-percent chlorhexidine following *in-vivo* instrumentation and irrigation with 1.0-percent sodium hypochlorite would enhance the rate of successful disinfection of the root canal system. Patients were selected with necrotic single rooted teeth with radiographic evidence of periapical osseous breakdown. After accessing and establishing working length of the 24 teeth chosen for experimentation, sterile paper points were used to acquire baseline cultures. All teeth were then instrumented with the same crown down preparation techniques using rotary nickel-titanium instrumentation. Initial irrigation of all teeth involved the delivery

of standardized volumes of buffered 1.0-percent sodium hypochlorite. However, half of the teeth (12) were then irrigated with 2.0-percent chlorhexidine after sodium hypochlorite was inactivated by sodium thiosulfate. Residual irrigation solution in all root canals was inactivated by L-α-lecithin in Tween 80. Sterile paper points were used to dry the canals and acquire samples for culturing. Cultured samples were incubated for a total of four weeks, with visual inspection taking place daily for the first seven days and weekly for the following three weeks. The results revealed that cultivatable bacteria were retrieved from seven out of 12 root canals irrigated only with buffered 1.0-percent sodium hypochlorite but in only one out of 12 canals when 2.0-percent chlorhexidine was added.

In 2004 Ercan et al.[250] compared the *in-vivo* antibacterial activity of 2.0-percent chlorhexidine gluconate to that of 5.25-percent sodium hypochlorite in infected root canals. Sixty single-rooted teeth diagnosed with pulpal necrosis, apical pathosis, or both were chosen for experimentation. Teeth were isolated, accessed, and cultured with sterile paper points. All sixty root canals were instrumented with K-type files and Gates Glidden burs with a step-back technique. During instrumentation, thirty of the teeth were irrigated with 2.0-percent chlorhexidine and the other thirty teeth were irrigated with 5.25-percent sodium hypochlorite. Sterile paper points were used to dry root canals and acquire bacteriologic samples for subsequent culturing. Access openings were sealed with zinc oxide-eugenol cement for 48 hours. Upon re-accessing the root canal system, bacteriologic samples were again acquired with sterile paper points. Cultures were subjected to microbiologic processing, which included incubation under anaerobic conditions. After colony-forming units (CFU) were counted, the results revealed no

significant differences in antibacterial activity between 2.0-percent chlorhexidine and 5.25-percent sodium hypochlorite. The authors concluded that both solutions could be recommended as irrigation solutions during endodontic therapy since they were able to significantly reduce microorganisms in root canals exhibiting pulpal necrosis, periapical pathoses, or both.

In 2007 Siqueira et al.[252] compared the *in-vivo* antibacterial efficacy of 2.5-percent sodium hypochlorite and 0.12-percent chlorhexidine during instrumentation and irrigation of teeth with necrotic pulps and apical periodontitis. Thirty four teeth exhibiting periapical radiolucencies were selected for the study. Teeth were isolated and accessed. Sterile paper points were inserted into the root canal system to determine baseline bacterial levels. All teeth were instrumented with hand and rotary instruments and irrigated with the adjunct of either 2.5-percent sodium hypochlorite (group one) or 0.12-percent chlorhexidine (group two). Apical sizes ranged between a size 50 to 60 dependent on canal anatomy and apical diameter of the root canal system. After instrumentation and irrigation root canals were dried with sterile paper points. Canals were flushed with sodium thiosulfate or a mixture of lecithin, Tween 80, and sodium thiosulfate to neutralize any residual irrigation solution. Post-instrumentation bacteriologic samples were acquired with sterile paper points for culturing. After cultures were incubated, colony forming units (CFSs) were counted and gene-sequencing analysis was performed to identify bacterial taxa. The results revealed that irrigation with 2.5-percent sodium hypochlorite yielded negative bacterial cultures in 37.5-percent of root canals treated and 50 percent of canals irrigated with 0.12-percent chlorhexidine were eradicated of cultivatable bacteria. No significant difference existed between the

two solutions. The bacterial load was significantly reduced in root canals after instrumentation and irrigation with sodium hypochlorite and chlorhexidine. The authors concluded that 2.5-percent sodium hypochlorite and 0.12-percent chlorohexidine were effective in reducing cultivatable bacteria in root canals during instrumentation, but no significant difference exists between the two solutions.

In 2009 Williamson et al.[253] compared antimicrobial susceptibility of monoculture biofilms of a clinical isolate of *Enterococcus faecalis* to various solutions of sodium hypochlorite and chlorhexidine. A failing root canal was used as the source of *Enterococcus faecalis* to be used in all biofilm assays. Biofilm was created in the laboratory on sterile glass microscope slides. The slides were then immersed in grouped centrifuge tubes containing standardized volumes of each of the irrigation solutions. Group one contained 2.0-percent chlorhexidine, group two contained 2.0-percent chlorhexidine and surface modifiers to lower viscosity (CHX-Plus), group three contained 6.0-percent sodium hypochlorite, group four contained less than 6.0-percent sodium hypochlorite and a wetting agent and proprietary surface modifiers (Chlor-XTRA), and group five contained sterile distilled water. Small stir bars were used to maintain slow stirring of solutions for one, three, and five minutes. Slides were immersed in neutralizing broth. The biofilms were scraped from glass slides and spiral plated onto agar. The number of viable bacteria was determined by sector plate counting. The results revealed sodium hypochlorite and chlorhexidine significantly reduced the amount of viable bacteria of biofilms compared to sterile distilled water. The chlorhexidine groups (groups one and two) reduced the colony forming units (CFUs) in biofilms by three to four orders of magnitude. The sodium hypochlorite groups (group

three and group four) reduced the colony forming units (CFUs) in the biofilms by seven to eight orders of magnitude. There were no statistically significant differences between group one and two or between groups three and four. Sodium hypochlorite with or without wetting agents and proprietary surface modifiers (Chlor-XTRA) exhibited significantly superior efficacy against *Enterococcus faecalis* biofilms when compared to 2.0-percent chlorhexidine with or without surface modifiers (CHX-Plus) after one-minute and three-minute exposures. The addition of surface modifiers did not seem to improve the bactericidal efficacy of sodium hypochlorite or chlorhexidine against biofilms of *Enterococcus faecalis*.

Ethylenediaminetetraacetic Acid (EDTA)

Ethylenediaminetetraacetic acid is a common chelating agent used in the irrigation of root canals during endodontic therapy due to its ability to remove smear layer.[194, 254-258] Chelating agents are chemical that bind to and inactivate specific metal ions to form soluble complexes. In the root canal system, EDTA binds to calcium ions of hydroxyapatite leading to dissolution of the inorganic component of dentin.[194] The resultant demineralization process results in removal of smear layer and enlargement of dentinal tubules.[259, 260] The coronal and middle thirds of the root canal wall are more susceptible to demineralization mainly due to limitations in access of solution, reduction of size and density of dentinal tubules, and sclerosis of dentinal tubules in the apical aspects of the root canal system.[194, 261-264] Also, dentinal tubules in the apical aspect of the root canal system are often sclerotic. Since chelating agents do not remove organic components, EDTA must rely on an organic tissue solvent such as sodium hypochlorite to help facilitate complete debridement of the root canal system.[2, 3]

In 1983 Yamada et al.[35] compared the cleanliness of instrumented root canal walls after irrigation with several chelating agents. Forty extracted single-rooted human teeth were divided into seven groups of five and a control group. All root canals were instrumented with a combination of Gates-Glidden drills for coronal flaring and K-type files for apical enlargement. Master apical file size of at least #50 was established in all canals. One ml of irrigation solution was delivered between file transitions by a 23-gauge needle placed as far apically as possible without binding. All groups except the negative control group were irrigated with 5.25-percent sodium hypochlorite during instrumentation. After instrumentation all root canals were irrigated with regimens consisting of various irrigation solutions. Group one (control) was flushed with 20 ml of physiological saline solution. Group two was irrigated with 20 ml of 5.25-percent sodium hypochlorite. Group three was irrigated with 20 ml of 17-percent EDTA. Group four was irrigated with 20 ml of 8.5-percent EDTA. Group five was irrigated with 20 ml of 25-percent citric acid. Group six was irrigated with 10 ml of 17-percent EDTA followed by 10 ml of 5.25-percent sodium hypochlorite. Group seven was irrigated with 10 ml of 8.5-percent EDTA followed by 10 ml of 5.25-percent sodium hypochlorite. Group eight was irrigated with 10 ml of 25-percent citric acid followed by 10-ml of 5.25-percent sodium hypochlorite. All root canals were dried and teeth were decoronated. Roots were longitudinally sectioned with hammer and chisel. Specimens were dried, sputter coated, and subjected to scanning electron microscopy. Photomicrographs were acquired at 50X, 700X, and 1500X magnifications. Three blinded examiners independently scored the photomicrographs according to presence or absence of soft

tissue debris, hard tissue remnants, and smear layer. The results led the authors to the following conclusions:

1) Root canal walls are not effectively cleaned with saline solution alone.
2) Superficial debris was removed by 5.25-percent sodium hypochlorite, but smear layer was not removed.
3) All chelating agents effectively removed smear layer but did not remove all superficial debris.
4) The most effective removal of superficial debris and smear layer from root canals walls occurred after irrigation with 10 ml of 17-percent EDTA followed by 10 ml of 5.25-percent sodium hypochlorite.

In 1987 Baumgartner and Mader[256] compared the debridement efficacy of instrumentation and irrigation of extracted single-rooted teeth with 0.9-percent saline solution (group one), 5.25-percent sodium hypochlorite (group two), 15-percent EDTA (group three), and the combination of 5.25-percent sodium hypochlorite and 15-percent EDTA (group four). After decoronation, all roots were sealed by silicon impression material in rubber hosing. Only the facial aspect was instrumented in half of the match-paired teeth in each group, while the lingual aspect was instrumented in the other half of the match-paired teeth of each group. K-type files were utilized in the instrumentation to an apical size of 50. A standardized irrigation protocol was implemented delivering standardized volumes of solution with a 27-gauge needle. Sterile water was used as a final irrigation solution in all root canals to terminate any solvent action and prevent precipitate formation. The total time of chemomechanical preparation and volume of irrigation solution delivered was recorded. Roots were removed from silicon impression

material and longitudinally sectioned. Scanning electron microscopy was used at various magnifications to evaluate the amount of superficial debris remaining on root canal walls and to compare the characteristics of the instrumented and uninstrumented halves of the canals. Results revealed a smear layer present on the instrumented surfaces of root canals irrigated with 0.9-percent saline and 5.25-percent sodium hypochlorite. A large portion of the smear layer was demineralized from instrumented surfaces by 15-percent EDTA, and some of the orifices of dentinal tubules were exposed. However, a residual layer exhibiting a fibrous texture covered a majority of the root canal wall. Pulpal remnants and predentin were completely removed from uninstrumented canal walls by 5.25-percent sodium hypochlorite. However, 0.9-percent saline and 15-percent EDTA left predentin and pulpal remnants on the uninstrumented root canal walls. The alternating delivery of 5.25-percent sodium hypochlorite and 15-percent EDTA resulted in complete removal of predentin and pulpal remnants from uninstrumented surfaces and smear layer from instrumented root canal walls. Exposed calcospherites on the uninstrumented root canal walls also exhibited an eroded appearance.

In 2002 Niu et al.[265] evaluated dentinal walls of root canals instrumented and irrigated with EDTA and sodium hypochlorite. Twenty-five single rooted extracted human teeth were chosen for the study. A standardized rotary nickel titanium instrumentation protocol was implemented. Teeth were divided into five groups dependent on final irrigation solution chosen. Group A was irrigated with 6.0-percent sodium hypochlorite for two minutes, group B with 15-percent EDTA for one minute, group C with 15-percent EDTA for one minute followed by 6.0-percent sodium hypochlorite for two minutes, group D with 15-percent EDTA for three minutes, and

group E with 15-percent EDTA for three minutes followed by 6.0-percent sodium hypochlorite for two minutes. Standardized volumes of irrigation solutions were utilized with standardized irrigation regimen using a 27-gauge needle for delivery. Roots were longitudinally sectioned and dried. Scanning electron microscopy was utilized to evaluate the remaining debris on root canal walls at one, three, and six mm from the apex. A three-score grading system was utilized, scoring residual debris amount as none (0), minimal (1), or moderate and heavy (3). The results that dentin of root canal walls irrigated only with 15-percent EDTA appeared smooth and plane with regular and separate dentinal tubule orifices. However, when root canals were irrigated with EDTA followed by sodium hypochlorite, dentin appeared eroded and dentinal tubule orifices were coarse and asymmetrical. Dentinal tubule diameter was significantly larger in root canals irrigated with EDTA followed by sodium hypochlorite as compared to EDTA alone. There was a significant difference between group B and C as well as between groups D and E. There was a significant reduction in residual debris on root canal walls irrigated with a combination of EDTA followed by sodium hypochlorite as compared to EDTA alone. The authors concluded that debridement efficacy of 6.0-percent sodium hypochlorite followed by 15-percent EDTA is superior to that of 15-percent EDTA alone, but at the expense of accelerated dentinal erosion.

Manufacturers often add antiseptics, surfactants, and other proprietary components to EDTA formulations in attempts to enhance its efficacy. Specifically, Sybron Dental Specialties™ markets a product called SmearClear™ which contains 17-percent EDTA, a cationic surfactant called cetrimide, and proprietary anionic surfactant(s).[257, 266] Cetrimide is a quaternary ammonium compound and a cationic

detergent.[266] This surfactant also possesses antifungal properties as well as bactericidal properties versus gram negative and gram positive microorganisms, specifically Enterococcus faecalis.[266-269] In addition cetrimide may alter the mechanical stability of biofilm by weakening the cohesive forces, and disrupting its self-produced extracellular polymeric substance (EPS) matrix.[268, 270] Since cetrimide is a surfactant, by definition it readily lowers the surface tension of a liquid, which may improve access and flow of solution into areas of impeded access, such as the apical extent of narrow root canals.[268, 271, 272] It has also been shown that the addition of surfactants may allow for increased penetration of irrigation solution into dentinal tubules during instrumentation.[273] In theory, this should lead to enhanced cleaning efficiency in the root canal system, with more efficacious removal of smear layer.[255]

In 2007 Lui et al.[255] compared the *in-vitro* efficacy of SmearClear™ to 17-percent EDTA in the removal of the smear layer in the apical third of the root canal system. Seventy-five extracted mature single-rooted human premolars were decoronated and randomly distributed to five groups of 15 teeth. A standardized instrumentation technique was initially utilized with all root canals using ProFile nickel-titanium rotary files with a crown down technique and K-type hand-files for apical instrumentation to a size 40. Root canals were irrigated with 1.0-percent sodium hypochlorite between each file transition. The final irrigation regimen differed among the five groups with irrigation solution delivered with a 27-gauge needle to within one to two mm from working length. Group one was irrigated with 5 ml of 1.0-percent sodium hypochlorite for one minute followed by 5 ml of 1.0-percent sodium hypochlorite. Group two was irrigated with 5 ml of 17-percent EDTA for one minute followed by 5 ml of 1.0-percent sodium

hypochlorite. Group three was irrigated with 5 ml of 17-percent EDTA for one minute with ultrasonics followed by 5 ml of 1.0-percent sodium hypochlorite. Group four was irrigated with five ml of SmearClear™ for one minute followed by 5 ml of 1.0-percent sodium hypochlorite. Group five was irrigated with 5 ml of SmearClear™ with ultrasonics followed by 5 ml of 1.0-percent sodium hypochlorite. All instrumented and irrigated roots were longitudinally sectioned, dried, and gold sputtered. The middle and apical levels were evaluated under a scanning electron microscope using X1000 and X3000 magnification. Photographs were acquired at 2-mm and 6-mm measurements from the apical foramina of all specimens. Two blinded examiners independently evaluated the photographs scoring relative amounts of debris and smear present. The results revealed that the use of ultrasonics in combination with 17-percent EDTA improved smear layer removal, but that the addition of surfactants to EDTA in SmearClear™ did not result in enhanced smear layer removal.

In 2008 Khedmat and Shokouhinejad[257] compared the efficacy of SmearClear™, 17-percent EDTA, and 10-percent citric acid in combination with 5.25-percent sodium hypochlorite in smear layer removal in the coronal, middle, and apical one thirds of the root canal system after instrumentation. Forty-eight extracted, single-rooted human teeth were decoronated and randomly divided into four groups of twelve. A standardized instrumentation technique was implemented with the use of two nickel-titanium rotary instruments ending with a size 30 at 0.05-taper. Each root canal was irrigated with 2 ml of 5.25-percent sodium hypochlorite between each file transition. Final irrigation solution and regimen varied among the four groups, but all solutions were delivered with a 30-gauge needle to a level of 1 mm to 2 mm from the working length. Group one

(control) was irrigated with 1 ml of 5.25-percent sodium hypochlorite followed by 3 ml of 5.25-percent sodium hypochlorite. Group two was irrigated with 1 ml of SmearClear™ for one minute followed by 3 ml of 5.25-percent sodium hypochlorite. Group three was irrigated with 1 ml of 17-percent EDTA for one minute followed by 3 ml of 5.25-percent sodium hypochlorite. Group three was irrigated with 1 ml of 10-percent citric acid for one minute followed by 3 ml of 5.25-percent sodium hypochlorite. All roots were longitudinally sectioned with a diamond disc and chisel. Specimens were mounted, gold sputtered, and evaluated under a scanning electron microscope. Photographs were acquired at X1000 and X2000 magnification at the coronal, middle, and apical one thirds of each specimen. The relative amount of remaining spear layer on root canal walls of all specimens was evaluated twice by a single, blinded endodontist using a three-score system. The results indicated that SmearClear™, 17-percent EDTA, and 10-percent citric acid provided root canal walls cleaner than 5.25-percent sodium hypochlorite (control). There were no statistically significant differences between SmearClear™, 17-percent EDTA, or 10-percent citric acid in smear layer removal at the coronal, middle, and apical thirds of root canals. All solutions were unable to completely remove the smear layer in the apical third of root canals. The authors concluded that the addition of surfactants to EDTA in SmearClear™ did not increase the efficacy of EDTA to remove smear layer from the walls of root canals.

EDTA exhibits minimal antibacterial activity, but on direct exposure for extended periods of time, it can bind with metal ions from the cell envelope of bacteria causing release of their surface proteins and even bacterial death.[2] Also, removal of the smear layer enhances the antibacterial effect of locally used disinfecting agents such as sodium

hypochlorite and chlorhexidine by allowing for penetration into deeper layers of dentin.[32, 274] Although EDTA does not remove organic material it can remove contaminated inorganic material, which contributes to eradication of bacteria from the root canal system.[2]

In 1985 Bystrom and Sundqvist[34] compared the antibacterial effects of 0.5-percent sodium hypochlorite, 5.0-percent sodium hypochlorite, and 5.0-percent sodium hypochlorite with 15-percent EDTA. Sixty teeth with diagnoses of pulpal necrosis and radiographic evidence of periapical osseous breakdown were chosen for the study. All teeth were placed in groups of 20, depending on irrigation solutions utilized. Group one was irrigated with 0.5-percent sodium hypochlorite, group two with 5.0-percent sodium hypochlorite, and group three with 5.0-percent sodium hypochlorite followed by 15-percent EDTA. Standardized instrumentation and irrigation protocols were implemented and bacteriologic samples were acquired at the beginning of three appointments. Samples were acquired with paper points and cultured under aerobic and anaerobic conditions. The sheer number of bacterial cells cultured was analyzed from samples acquired during the first and second appointments with no attempt at identification of isolated bacteria. However, bacterial species were attempted to be identified from samples acquired from root canals at the third appointment. The results indicated no significant difference in antibacterial effect of 0.5-percent sodium hypochlorite compared to 5.0-percent sodium hypochlorite, but that the combination of 5.0-percent sodium hypochlorite and 15-percent EDTA yielded a statistically significant reduction in bacteria. Approximately 80-percent of bacterial cultured from samples acquired at the third appointment were anaerobic in nature, and no specific bacteria seemingly exhibited

resistance to treatment. The authors also observed that bacteria surviving instrumentation and irrigation quickly increased in quantity between appointments in the absence of intracanal medicament.

EDTA exhibits self-limiting properties seemingly due to pH changes during the demineralization of dentin. Like most chelators, EDTA has a relatively neutral pH under neutral conditions. During demineralization, calcium is exchanged from the dentin by hydrogen. The resultant release of acid causes protonation of EDTA inhibiting its demineralization effect on dentin over time. However, the acid subsequently continues to form a complex with calcium ions in hydroxyapatite continuing dissolution of dentin. Over time, acid accumulates and protonation of EDTA prevails leading to decrease in rate and eventual cessation of demineralization. Theoretically, dentin demineralization is ended when all available ions have been bound, making EDTA a self-limiting solution.[194, 275] However, studies have suggested EDTA possessing long-lasting residual demineralization effects leading to deleterious erosion of peritubular and intratubular dentin.[194, 256, 258, 265, 276]

In 2002 Calt and Serper[258] examined the effects of 17-percent EDTA on smear layer removal from dentin after one and ten minute applications. Six extracted single-rooted human teeth were instrumented with K-files and Gates-Glidden drills and irrigated with 5.0-percent sodium hypochlorite. The coronal and apical one thirds of roots were removed. The remaining 5-mm middle third was longitudinally sectioned. One of the halves was irrigated with 10 ml of 17-percent EDTA for one minute while the other half was irrigated with 10 ml of 17-percent EDTA for 10 minutes. All sections were again irrigated with 10 ml of 5.0-percent sodium hypochlorite, dried, and evaluated under

scanning electron microscopy (SEM). The results revealed root sections irrigated with 17-percent EDTA for one minute followed by 5.0-percent sodium hypochlorite were completely devoid of smear layer and dentinal tubules appeared patent. A slight peritubular and intertubular erosive effect was noted in two out of six of the sections. The smear layer was also completely removed from root sections irrigated with 17-percent EDTA for 10 minutes followed by 5.0-percent sodium hypochlorite. However excessive peritubular and intratubular erosion was observed that led to conjugated tubular orifices and widening of tubular diameters. In addition, enlargement of dentinal tubular orifices with deterioration of dentinal surfaces was observed in two of the six sections. When the erosion was allowed to progress the diameter of the dentinal tubules surpasses the diameter of the actual tubule, yielding a "wormhole" appearance. In some areas of most of the sections exposed to 17-percent EDTA for 10 minutes, the intertubular dentin was completely destroyed leaving adjacent tubules in close proximity. These sections also exhibited tubule orifices with diameters approximately twice the size of those sections subjected to one minute of 17-percent EDTA. Other studies have revealed the erosive effects of prolonged exposure of EDTA to dentin,[194, 256, 265] and Patterson showed that EDTA-induced dentin demineralization lasted up to five days.[276]

In 2008 Saito et al.[254] compared the efficacy of smear layer removal from root canals irrigated with 17-percent EDTA for one minute or less. Forty, extracted, single-canal, anterior and premolar human teeth were decoronated and randomly separated into groups of three experimental groups of ten. A standardized instrumentation technique was implemented with ProTaper and ProFile nickel-titanium rotary instruments in a crown-down fashion to an apical diameter of size 40. All root canals were irrigated with

1 ml of 6.0-percent sodium hypochlorite between file transitions. Final irrigation solution varied between the three experimental groups, but a 30-gauge, side-vented irrigation tip (Max-I-Probe) was progressed to 1 mm short of working length in all groups. Group one was irrigated with 17-percent EDTA for one minute, group two was irrigated with 17-percent EDTA for 30 seconds, and group three was irrigated with 17-percent EDTA for 15 seconds. All three groups were irrigated with a final rinse of 3 ml of 6.0-percent sodium hypochlorite. Positive control teeth were irrigated with a final rinse with 10 ml of 17-percent EDTA over a period of ten minutes followed by irrigation with 3 ml of 6.0-percent sodium hypochlorite. Negative control teeth were irrigated with a final rinse using only 3 ml of sodium hypochlorite. All roots were longitudinally sectioned with a diamond disc and chisel. Specimens were dried, mounted, sputter-coated, and evaluated under a scanning electron microscope at X350 magnification. Photographs were acquired at the coronal, middle, and apical one thirds. Three endodontists blindly and independently evaluated the relative amount of smear layer remaining in each section of each specimen using a three-score system. The results revealed that final irrigation using only 5.25-percent sodium hypochlorite (negative control) left a heavy smear layer present in the coronal, middle, and apical sections of the root canal walls. A majority of dentinal tubules were closed and covered with smear layer and debris. The root canals irrigated with 17-percent EDTA for 10 minutes followed by 6.0-percent sodium hypochlorite (positive control) exhibited walls completely free of smear layer, but at the expense of severe intertubular and peritubular erosion. The results also revealed that decreasing the irrigation time with 1 ml of 17-percent EDTA to 30 or 15 seconds, significantly decreased the efficacy of smear layer removal as compared to irrigation with 17-percent

EDTA for one minute. The authors recommended that root canals be irrigated with a final rinse of 17-percent EDTA for one minute followed by 3 ml of 6.0-percent sodium hypochlorite with solutions being delivered with a 28-gauge or 30-gauge side-vented needle placed 1 mm from working length.

Hulsmann[194] critically examined the literature regarding efficacy, applicability, safety, and methodology for use of chelating agents, specifically EDTA, during endodontic therapy. The author concluded that chelating agents such as EDTA, citric acid, and tetracycline, should be implemented into root canal therapy due to reduction in amount and removal of smear layer produced during cleaning and shaping, and increased penetration of sodium hypochlorite into dentin. However, since chelating agents do not dissolve organic matter and exhibit low antibacterial effect, they should not replace sodium hypochlorite but instead be used in combination. The author suggested that concentration of solution and duration of application seemed to be more important factors than the specific solution chosen. The efficacy of chelating agents such as EDTA is directly related to the amount of available solution and canal-wall surface area, both of which may be reduced in calcified and narrow canals. This along with changing dentinal tubule configuration, size, and shape at different positions along the root canal wall, lead to a decrease in efficacy from the canal orifice towards the apex. Chelating agents such as EDTA can be safely delivered during careful irrigation of the root canal system with minimal risk of damage to periapical tissues.

IRRIGATION DELIVERY AND DYNAMICS

Irrigation does not lead to complete debridement and disinfection of the root canal system, despite the technique implemented.[3] Multiple studies have suggested that bacteria and debris remain within the root canal system, specifically in the apical one third, even after meticulous chemo-mechanical debridement.[23-26, 30, 36-38, 40-43, 277-279] Endodontic instruments are unable to plane all walls of the complex root canal system, and sodium hypochlorite is unable to dissolve tissue from these uninstrumented areas.[23-26, 159] Also, the traditionally syringe and needle method of passively delivering irrigation solution to the root canal system is plagued with shortcomings.[1, 3, 146] The root canal preparation must incorporate coronal flaring and/or increased size of apical instrumentation to facilitate irrigation solutions to reach the apical portion of the canal.[3, 183-185, 280-282] In fact, the apical 5 mm of the root canal system may not be adequately flushed with irrigation solution unless enlarged to a size #30 to #40 file.[3, 183-185, 221, 281, 283] However, due to anatomic variations, it may not always be possible to flare and/or enlarge the root canal to an ideal diameter without removing excess dentin and weakening the root.[187] In addition, irrigation of the canal is limited to approximately 1 mm beyond the irrigation tip, promoting the placement of needles of small diameter in close proximity to the working length.[183, 200-202, 279] However, in roots that exhibit open apices or in the event that the irrigation needle binds, especially in such close proximity to the apical foramen, the risk of extrusion of irrigation solution is increased, which could to detrimental health effects and toxicity to host cells.[203-209] Also, frequent and large volumes of irrigation solution should be delivered to the root canal system to enhance debridement and disinfection.[35, 37, 213, 215, 228, 279, 283, 284] Smaller bore needles are more

prone to clogging and breakage and require more force applied to the plunger of the syringe to deliver similar amounts of solution compared to larger bored needles.[3, 200, 285, 286] Therefore, it may not be realistic to safely and effectively deliver high volumes of irrigation solution to the apical extent of the root canal system with traditional techniques, especially in narrow and curved canals.

As previously stated, the efficacy of root canal irrigation is affected by the size of the root canal preparation as well as the size of the irrigation needle used to deliver irrigation solution.[3, 183-185, 200-202, 221, 279-283]

In 1977 Ram[184] determined the minimal diameter of the root canal which would allow for *in-vitro* delivery of irrigation solution to the apex. Three groups of extracted, single-canal, human teeth with narrow canals were decoronated. Root canals were debrided, irrigated, and instrumented with files and reamers using 15-percent EDTA and frequent and repeated irrigation with water and 5.25-percent sodium hypochlorite. Apices were sealed with a double layer of sticky wax and carding wax. A file was inserted into the root canal from the coronal aspect and progressed until penetrating the apical wax seal. Root canals were flooded with a radiopaque material with the viscosity of water (Hy-Paque), and the apical foramen resealed with wax. Radiographs were acquired. An irrigation jig was constructed with a container of water connected to a tube which was also connected to an irrigation syringe loaded with a 25-gauge needle. The handle of the container of water was also connected to a pulley system, alloying for vertical height to be adjusted. Variation in height of container relative to specimen to be irrigated lead to variation in pressure of irrigation solution delivered to the syringe. The irrigation pressure approximated that applied in a clinical setting of root canal irrigation

with syringe and needle. A hose clamp was used to control irrigation time. Group one consisted of 24 teeth that were enlarged to an apical diameter of #25 file. Group two consisted of ten teeth that were enlarged to an apical diameter of a #40 file. Group three consisted of five teeth enlarged to an apical diameter of a #60 file. All groups were irrigated with 5 ml of saline at simulated clinical pressure. Group one also irrigated with 10 ml of saline at twice the simulated clinical pressure. All teeth were again radiographed to evaluate relative amounts of Hy-Paque remaining after irrigation of root canals of various apical diameters and irrigation delivery pressures. The results indicated that the Hy-Paque solution in the apical half of 22 of 24 root canals instrumented to a size #25 file (group one) was undisturbed. In eight out 10 root canals instrumented to a size #40 file (group two), the Hy-Paque solution was completely cleared from the root canal system. When five canals were instrumented to a size #60 file (group three) and irrigated with saline solution, all five canals were completely cleared of Hy-Paque solution. The author concluded that the most significant factor in maximizing efficacy of debris removal during irrigation is the diameter of the root canal, and that effective irrigation does not occur consistently unless root canals are enlarged to at least a size #40 instrument. He also suggested that small-diameter irrigation needles are more effective in debridement efficacy as they progress further apically allowing for better fluid exchange and cleaning.

In 1982 Abou-Rass and Piccinino[200] evaluated four irrigation methods to determine efficacy of dentinal debris removal from the root canal system. Narrow and curved mesial roots of 48 extracted mandibular molars were chosen for experimentation. The 24 teeth in group one were instrumented with the step-back technique to an apical

diameter of a size #25, and the 24 teeth in group two were instrumented to a size #40. During instrumentation, all canals were repeatedly irrigated with 2.5-percent sodium hypochlorite and RC Prep was frequently applied to files. All preparations were flared coronally and apical patency was maintained with a #15 file. Extracted teeth were grinded in order to simulate dentinal debris. The debris was mixed with radiopaque contrast medium and used to fill the root canal system with the adjunct of a high-speed suction tip placed at the apex. The apex was sealed with was and radiographs acquired. The same forty-eight teeth were used in each of the four irrigation groups. In group one tap water was placed in the pulp chambers with a 23-gauge endodontic irrigation needle, and then stirred in each canal with a #15 file. In group two a 23-gauge endodontic needle was placed in the canal as far as possible without binding and root canals were irrigated with tap water. In group three, root canals were irrigated with anesthetic solution from a 30-gauge needle and a standard anesthetic syringe. The needle was placed in the canal as far as possible without binding. In group four, the root canals were irrigated using a 23-gauge needle placed as far as possible without binding to deliver 3.0-percent hydrogen followed by 2.5-percent sodium hypochlorite. Radiographs were acquired and scored under magnifying glass to determine efficacy of flushing action of each irrigation group. The results indicated that irrigation with the 30-gauge anesthetic syringe (group three) was more effective in flushing dentinal debris from instrumented root canals to size #25 and #40 as compared to those irrigated with a 23-gauge endodontic needle or stirring the irrigation solution with a file (groups one, two, and four). The authors concluded that the irrigation needle must come in close proximity to material to be removed in order to be effective, and that the use of a 30-gauge anesthetic needle was more effective than a 23-

gauge Endo needle or stirring the irrigation solution with a file. They also concluded that narrow canals can be effectively irrigated when the cervical and middle thirds are tapered to allow progression of the irrigation needle to the apical one third of the root canal system.

In 1989 Druttman et al.[279] compared the effectiveness of irrigation solution replacement in simulated root canals using irrigation needles of various sizes. Clear polyester resin blocks were constructed with canals of three different sizes, and lines were drawn on the outside to delineate the coronal, middle, and apical one thirds of the root canal. Toluene dye was used to fill the simulated canals. Clear water was used as an irrigation solution, and delivered with a 23-gauge, 25-gauge, or 30-gauge needle in all three sizes of the root canal. The degree of dye displacement was then measured in the coronal, middle, and apical thirds and compared to standardized blocks with predetermined graded dilutions. The results revealed that the effectiveness of dye removal was related to size of needle with only the 30-gauge completely clearing the dye from the apical aspect of the simulated canal

In 2002 Bradford et al.[203] evaluated the apical pressured developed by needles used for root canal irrigation. Ten root relatively straight root canals of extracted human teeth were allocated to two groups. The first group consisted of ovoid canals, while the second group exhibited round canals. Pulp tissue was removed from the root canals of all specimens with a barbed broach. Root canals were manually instrumented with K-type files starting a size #15 and continuing in successive order to a size #40. Each file was progressed 1 mm beyond the apices of roots. Tests were performed on root canals after each increase in file size with varying irrigation needles. Plastic tubing was luted to all

root ends and connected to a pressure gauge. A Stropko air syringe equipped with the test needle was progressed into each root canal to a level of apical binding. Air was expressed at a regulated pressure of five pounds per square inch (psi). This test was repeated for all root canals with the irrigation needle tips withdrawn 1 mm from the point of apical binding. The test needles consisted of Max-I-Probe side-vented, closed-end irrigation needles and Monoject end-notched irrigation needles. The diameters of the Maxi-I-Probe needles were 23-gauge, 24-gauge, 25-gauge, 28-gauge, and 30-gauge. The diameters of the Monoject needles were 23-gauge and 27-gauge. A Timemeter Flowmeter was used to directly measure the different air flow rates. The results revealed that when canals were instrumented to a size 30 or higher through the apex, the apical pressure generated was significantly higher. Also, when the needle was bound within the root canal significantly higher apical pressures were generated. In fact, needle size, needle design, nor canal shape significantly changed the apical pressure generated when the needle was bound. Larger bore needles generated significantly more apical pressure when the needle was placed 1 mm short of binding. Larger canal diameters were allowed significantly greater generation of apical pressure with specific risk occurring when apical diameter surpassed a size #25 file. No statistically significant difference was observed in generated apical pressure generated by various needle-tip designs or needle diameters. When needle type and canal diameter were compared no significant difference was observed in generated apical pressure between the three types of irrigation needles. No needle type was superior in all cases, but smaller canals were generally less likely to permit high apical pressures.

In 2006 Zehnder[218] suggested that small-diameter side-vented needles with "safety tips" could be safely progressed to working length or 1 mm short during irrigation. Moreover, he recommended that these needles should be progressed to this level during the irrigation of non-vital teeth with periapical radiolucencies.

In 2007 Vinothkumar[287] evaluated the influence of three-different irrigating needle-tip designs in removing bacteria from instrumented root canals. Thirty extracted single-rooted human canines were autoclaved and root canals were prepared to size 60 at working length with ProFile nickel-titanium rotary file system in a crown-down technique. Root canals were irrigated with 5.25-percent sodium hypochlorite between instrument transitions, and the smear layer was removed with ultrasonic treatment using 17-percent EDTA followed by 5.25 percent sodium hypochlorite. Distilled water was then delivered to all root canals to neutralize irrigation solutions. The root apices were coated with fingernail varnish and teeth were autoclaved. All root canals were then inoculated with genetically engineered luminescent *Escherichia coli* bacterial strains. The instrumented specimens were then randomly divided into three groups of ten. Group one was irrigated with a 25-gauge, side-vented, end-closed irrigation needle. Group two was irrigated with a 25-gauge with double, side-vented portals of exit at different levels from the tip. Group three was irrigated with a 25-gauge hypodermic needle. All needles were placed 1 mm short of working length within root canals during irrigation with 6 ml of saline. Root canals were immediately aspirated and dried with sterile paper points immediately following irrigation. Bioluminescence was measured prior to bacterial inoculation, immediately after inoculation, and after irrigation with 6 ml of saline. The results revealed a significant reduction in bacteria in each irrigation group after irrigation

with 6 ml of saline solution. The 25-gauge, single side-vented, closed-end needle was significantly more effective than the double side-vented and hypodermic needles in mechanical reduction of bacteria during irrigation of instrumented root canals.

In 2010 Shen et al.[288] investigated the effect of irrigation needle tip design on irrigation solution flow pattern. The authors used a three-dimensional computational fluid dynamics (CFD) model and validated results with an *in-vitro* irrigation model in a simulated straight root canal in a resin block. Dynamic flow distribution was recorded and analyzed during irrigation of the simulated canal with a 27-gauge notched irrigation tip and a 27-gauge side-vented, open-ended irrigation tip placed 3 mm and 5 mm from the apex. Computer fluid dynamic (CFD) analysis was performed on the above mentioned needle-tip designs in addition to a design with a beveled tip and a design with a side-vent with a closed-end at the tip. Calculations were made using CFD to determine flow velocity at the wall, flow velocity distribution, and apical pressure within the simulated root canal. The results suggested that flow patterns generated by the *in-vitro* model and the CFD analysis were in close agreement. The side-vented, closed-end needle exhibited the lowest apical pressure, and the beveled needle exhibited the highest apical pressure. Side-venting reduced apical pressure by approximately 17-percent to 19-percent, and closing the end lead to a 2.5-fold to 3.0-fold decrease in apical pressure. However, the flow on the opposite-side to the vent in the closed-end needle approached zero. The authors suggested that the side-vented, closed-end needle may enhance safety of irrigation in the apical aspect of the root canal system.

As previously discussed, multiple studies have suggested that the expression of irrigation solution is limited to approximately 1 mm beyond the irrigation tip.[183, 200-202]

Several authors have suggested that *in-vivo*, the root canal acts like a "closed-end channel," with the apex being the closed-end. Therefore, gas becomes trapped at the apical extent of the canal during irrigation delivery creating a "vapor lock effect," and limiting the expression of irrigation solution.[201, 202, 221, 289]

In 1971 Senia[221] evaluated the solvent action of 5.25-percent sodium hypochlorite on pulp tissue from the root canals of extracted, mandibular molars to determine the solvent action. Standard root canal preparation techniques were implemented on the two canals of the mesial root. Full-strength, 5.25-percent sodium hypochlorite was used as an irrigation solution in one canal while normal saline solution was used as a control in the other canal. Irrigation took place for time intervals of 15 and 30 minutes. Roots were cross-sectioned at 1-mm, 3-mm, and 5-mm levels from the apices. The sections were then stained, and examined at X100 magnification via light microscopy. An evaluation was performed of the root canal contents and any isthmus present between the two canals. The observations suggested that the effervescence of the sodium hypochlorite prevented fresh solution from reaching the apical extent of the root canal system. The "bubbles" occupied the limited space available and pushed replenished solution away from the apex. Fluid could not be adequately forced into the confined space of the apical 1 mm to 3 mm of the root canal system even with a sharp-pointed instrumented. The author concluded that the narrow and curved root canal may be impossible to adequately clean in the apical 5 mm.

In 1983 Chow[183] investigated the influence of needle size, depth of insertion, and pressure of irrigation on the irrigating efficacy of the apical portion of simulated root canals. Simulated root canals were fabricated with glass tubes of standardized diameters

and tapers similar to various reamers. Standardized quantities of insoluble particles of bead-form gel were stained with ink and used to intracanal particles. The sticky particles simulated bacteria sticking to root canal walls. Irrigation was performed with 0.9-percent sodium chloride from a syringe equipped with either a 23-gauge or 25-gauge hypodermic needle. An apparatus was created in which weights positioned on a platform were applied to the plunger of the irrigating syringes during irrigation so that a standardized volume of solution was delivered over a given time period. In the first experiment, the relationship of the depth of needle insertion to the apical extent of irrigation was evaluated. Glass tubes of sizes corresponding to reamer sizes of #50, #60, and #70 were utilized. In the second experiment the correlation of needle size to irrigation efficacy was evaluated. Experiment two consisted of repeating experiment one with the use of a 25-gauge needle. In determining the apical extent of irrigation solution, a sharp demarcation line was visualized on the glass tubes after irrigation representing the particle-saline interface. The results revealed minimal fluid exchange and displacement of debris beyond the tip of the irrigation needle. The authors concluded that the apical extent of effective irrigation was limited by the depth of insertion of the needle, and recommended progressing the irrigation needle as close to the apex as possible without binding. They also concluded that needles of small diameter were more effective than needles of large diameter, and recommended using flexible, 30-gauge needles in fine, curved canals. Most importantly, the authors observed that when an air bubble or column was present in the simulated glass root canals, the irrigation solution could not displace or bypass it. The authors suggested that these air bubbles may prevent irrigation solution, specifically

sodium hypochlorite, from reaching the apical foramen or even near the apex when irrigating root canals clinically.

In 2009 Boutsiokis et al.[202] used computational fluid dynamics (CFD) to evaluate the flow pattern of irrigation solution within a prepared root canal during delivered with a syringe and needle at various flow rates. A stereoscopic microscope was used to acquire images of a 30-gauge, side-vented irrigation needle. Actual measurements of the irrigation needle, measurements from the stereoscopic images, and calibrations from previous studies were used to create a Computational Fluid Dynamics (CFD) model. The root canal was also simulated to mimic that of a central incisor. A cone shape was fabricated 19 mm in length with an apical diameter of 0.45 mm and an orifice diameter of 1.59 mm. This shape coincided with the final shape and size of a root canal prepared with a rotary nickel-titanium of size #45 with 0.06 taper. An apical terminus was simulated with an inverted cone orientation. The apical constriction measured 0.3 mm in diameter and the apical foramen measured 0.35 mm in diameter. The simulated needle was centered in the root canal 3 mm from the working length during delivery of irrigation solution. Five selected flow rates were utilized for calculations. Velocity and turbulence quantities were evaluated along the domain. The results revealed laminar flow of irrigation solution with low velocity in the middle and coronal aspects of the canal. The main flow of irrigation solution was directed from the side vent of the needle in a lateral direction. It then followed a curved path around the needle tip leading to a small counterclockwise vortex with limited apical penetration. Solution was eventually directed towards the canal orifice, but significant turbulence was not observed coronally to the side vent of the needle during experimentation. Irrigation solution located at the

distal aspect of the needle, immediately apical to the side-vent, exhibited virtual stagnation. When velocity of irrigation solution on the inside of the needle was increased, the efficiency of irrigation solution was also increased. The authors concluded that creation of turbulent flow leads to more efficient replacement of irrigation solution. However, even when maximum inlet velocity was evaluated, replacement of irrigation solution was limited to 1.0 mm to 1.5 mm apically to the needle tip. The authors also indicated that the presence of "air bubble entrapment" in the most apical aspect of the root canal may further decrease the efficiency of apical irrigation.

In 2009 de Gregorio et al.[201] evaluated the fluid dynamics of irrigation solutions delivered to the root canals of extracted human teeth mounted in clear silicon to simulate surrounding periodontal tissues. Root canals were instrumented with a standardized protocol using nickel-titanium rotary files. Irrigation of canals was performed with a 27-gauge side-vented irrigation needle. Different experimental groups were irrigated with various irrigation regimens, but all groups were irrigated with a final rinse of 5.25-percent sodium hypochlorite combined with a contrast solution. Samples were assessed by direct observation under a dental operating microscope, and by radiographic evaluation. The results revealed a "vapor lock" at the apical extent of root canals irrigated only with a 27-gauge side-vented irrigation needle. The authors concluded that the "vapor lock" was created by gases in the apical region of the root canal, which inhibited further fluid penetration. Thus, positive pressure irrigation with a side-vented irrigation needle was limited to the approximate level of the needle tip.

In 2010 Tay, et al.[289] evaluated the effect of "vapor lock" on debridement efficacy of root canals irrigated with a positive pressure side-vented needle delivery system in

"open" versus "closed" root canal systems. Twenty-eight extracted single-rooted human teeth with narrow and wide canals were decoronated and dispersed into two experimental groups. In group one, a closed system was simulated. The cementum all roots was coated with tray adhesive, and the apices were sealed with hot, flexible glue and placed in PVS-filled plastic tubes. In group two, an open system was simulated. The apical foramen was enlarged to a size 30 file and a straw segment was glued to the external root surface of the apex. Free communication was permitted between apical extent of root canal and external environment. Roots of both groups were instrumented with a standardized, crown-down technique ending with a size 50 file. All root canals were irrigated by using 30-gauge Max-I-Probe side-vented, closed-end needle progressed to 1 mm short of working length. One ml of 1.3-percent sodium hypochlorite was delivered between each file transition. One ml of Biopure MTAD was then delivered as a final irrigation solution and left undisturbed in the root canal system for five minutes. All canals were again irrigated with 1 ml of Biopure MTAD, followed by 5 ml of deionized water. Root canals were then dried with sterile paper points, accesses were temporized, and roots were removed from PVS impression material. Two teeth from each group were chosen for micro-CT analysis of gas entrapment. A contrasting medium (cesium chloride) was delivered to the root canals by placing the 30-gauge Max-I-Probe side-vented, closed-end needle progressed to 1 mm short of working length. Ten roots from each group were sectioned longitudinally, fixed, dehydrated, sputter-coated, and examined with scanning electron microscopy. Five representative micrographs were acquired at X2000 magnification of the coronal (11 mm to15 mm), middle (5 mm to 10 mm), and apical (0 mm to 5 mm) sections of each longitudinal section of root canal. Two

blinded examiners independently examined the micrographs scoring with five-level smear layer retention and five-layer debris retention system. One root from each group was also fixed in formaldehyde, demineralized, and embedded in paraffin wax. Serial sections were prepared at 0.5 mm to 1.0 mm from the anatomic apex, stained, and histologically examined under light microscopy at X40 magnification. The observations from the micro-CT scans of fluid filled canals showed that contrasting medium did not reach the apex in the roots exhibiting a "closed" system (group one). However, roots of the "open" system allowed free fluid flow to the apical extent of the root canal system. The "vapor lock" present in the closed prevented fluid from travelling beyond the apical 0.5 mm to 1 mm of the root canal. SEM analysis also revealed statistically significant reduction debris in the open system at the coronal, middle, and apical segments of the root canal. Specifically, the apical 0.5-mm to 1.0-mm apical sections of root canals from the "open" system (group two) revealed clean canal space compared to the incompletely cleared canal walls of the "closed" system (group one). The authors concluded root canals probably exist as a "closed" system clinically, and that *in-vitro* studies evaluating debridement efficacy of root canals in which "open" systems are designed should be interpreted with caution.

In the event that a "vapor lock" does actually occur clinically in the apical aspect of the "closed system" of the root canal, irrigation efficacy will be negatively affected.[183, 202, 221, 290] Irrigation with negative pressure has been advocated to safely enhance debridement and disinfection of the apical aspect of the root canal system.[44-46, 290-292]

In 2006 Fukumoto and Yoshioka[45] evaluated the efficacy of smear layer removal from root canal walls with the use of a new root canal irrigation technique that

implemented negative pressure via intracanal aspiration. Thirty five extracted human maxillary canines were selected for experimentation. All root canals were instrumented with a standardized technique irrigating with 6.0-percent sodium hypochlorite between each file transition. Gates Glidden drills and GT nickel-titanium rotary files ending with an apical preparation diameter of file size 20 with 0.1-taper. The apical 3 mm of each root was removed, and root canals were washed with distilled water. Root canals were filled with silicone and secured in a plastic case filled with red, normal saline agar. The red saline agar was used to examine apically extruded sodium hypochlorite. Silicon within root canals was removed, and specimens were randomly allocated to one control and four experimental groups. No further instrumentation or irrigation was performed on the control group. Irrigation solution was delivered via tubing pump at a constant, standardized flow rate. Each root canal was irrigated with 9 ml of 14-percent EDTA for three minutes followed by 6 ml of sodium hypochlorite for two minutes. Groups one and two were irrigated using an intracanal aspiration technique. The tip of an injection needle was placed in the coronal aspect of the canal approximately 12 mm from the apical aspect of the resected root. A second needle of outer diameter 0.55 mm and inner diameter 0.30 mm was connected to an apical foramen locator and used for all intracanal aspiration. The flattened tip was positioned between 2 mm from the resected root end in group one and 3 mm from the resected root end in group two. A constant, standardized aspiration pressure was maintained via suction unit. Groups three and four were irrigated with a conventional method. The irrigation needle was placed approximately 2 mm from the resected root end in group three and 3 mm from the resected root end in group four. The aspiration needle was positioned at the coronal aspect of the root, approximately 12 mm

from the resected root end. The color change of the saline agar was recorded by an image scanner, and magnitude of discolored area was calculated by computer analysis. Roots were removed from the mounting jig and washed with 10 ml of distilled water. The apical 5 mm of each root were longitudinally sectioned, dehydrated, sputter-coated, and evaluated under a scanning electron microscope. Photographs were acquired at 0.0 mm, 1 mm, 2 mm, and 3 mm from the apex at X500 magnification. Three blinded evaluators independently scored the photographs using a four-score system. The scoring criteria assessed relative number of dentinal tubules patent and relative dissolution of intertubular dentin (erosion). The results of SEM analysis revealed smear layer covering majority of the root canal wall in the control group with only a few dentinal tubules patent. Root canals that were irrigated with the intracanal aspiration technique in which the aspiration needle was placed within 2 mm from the resected root end (group one) exhibited significantly less residual smear layer. This group also exhibited minimal apical extrusion of irrigation solution. Irrigation with a conventional method, with the positive pressure irrigation placed approximately 2 mm from the resected root end (group three) produced statistically significant more apical extrusion of irrigation solution. The authors concluded that the intracanal irrigation technique was effective in removing smear layer from the apical aspect of apically resected root canals with negligible extrusion of irrigation solution.

The EndoVac is a negative pressure irrigation system that was invented by John Schoeffel.[47-50, 290, 293] The system generates negative pressure that draws irrigation solution apically via suction from the high-volume evacuation of the dental unit. The system is compromised of a Master Delivery Tip (MDT), MacroCannula, and

MicroCannula. The Master Delivery Tip delivers copious amounts of irrigation solution to the access opening while simultaneously evacuating debris and excess solution. The MacroCannula removes debris remaining in the canal from instrumentation as well as simultaneously delivered irrigation solution from the Master Delivery Tip. The MicroCannula evacuates microscopic debris and irrigation solution from the apical extent of the root canal, down to the level of the working length via its microscopic, laser-drilled holes.[47-50, 290, 293] The inventor suggests that the system is capable of removing gases that accumulate at the apical extent of the root canal system during irrigation. It has been theorized that the "vapor lock" effect is eliminated and apical debridement and disinfection of the root canal system is enhanced.[48, 290]

In 2007 Neilsen and Baumgartner[44] compared the apical debridement efficacy of the EndoVac system compared to standard needle irrigation of a root canal. Nineteen matched pairs of human incisors, canines, and premolars were chosen. Root surfaces were debrided, and occlusal surfaces were flattened to promote consistency of reference points. Tray adhesive was applied to external root surfaces and teeth were submerged into PVS housed in one-inch segments of surgical tubing. One tooth of each matched pair was irrigated with the EndoVac system (group one). The other tooth of the matched pair was irrigated with a standard irrigation regimen using a syringe equipped with a 30-gauge ProRinse side-vented, closed-end needle (group two). The same amount of time was spent irrigating both groups, and total volume of irrigation solution delivered was recorded. All teeth were instrumented with a standardized crown-down technique using a combination of Gates Glidden drills and ProFile Series 29 nickel-titanium rotary files. All canals were instrumented to a size #36 at working length or larger, with all matched

pairs possessing the same apical preparation diameter. A size #10 K-type file was used to maintain apical patency between each file transition. In the EndoVac group, 1 ml of 5.25-percent sodium hypochlorite was delivered with the Master Delivery Tip between each file transition. After instrumentation with the master apical file, the MacroCannula was used to remove debris and evacuate 5.25-percent sodium hypochlorite delivered to the root canal over a 30-second period by the Master Delivery Tip. The MicroCannula was used to remove debris and evacuate irrigation solution delivered to the root canal over a 30-second period by the Master Delivery Tip. During this process, the MicroCannula was progressed to working length for six seconds, retracted approximately 2 mm for six seconds, progressed to working length for six seconds, and so on for 30 seconds. Irrigation solution was left undisturbed in the root canal for 60 seconds. This process was repeated with 15-percent EDTA, and 5.25-percent sodium hypochlorite. The MicroCannula was then progressed to working length and used to evacuate irrigation solution from the canal. The other tooth of the matched pair (group two) was irrigated with 1 ml of 5.25-percent sodium hypochlorite using a syringe and 30-gauge ProRinse side-vented, closed-end needle between file transitions. The needle was needle was progressed "just short" of the binding point but no closer than 2 mm from the working length. Irrigation solution was delivered while the needle was moved in 1 mm to 2 mm constant apical-coronal movements. Once the canals were instrumented to the master apical file, sodium hypochlorite was delivered for 30 seconds and then left undisturbed in the canal for 60 seconds. Irrigation was initiated again delivering 5.25-percent sodium hypochlorite while moving the irrigation needle from 2 mm to 4 mm from the working length for 30 seconds. Irrigation solution was left undisturbed in the root canal for 60

seconds. This process was repeated with 15-percent EDTA and again with 5.25-percent EDTA. Irrigation solution was removed from the root canal by placing the irrigation needle 2 mm from the working length and retracting the plunger of the syringe. All teeth were removed from impression material and marked at 1 mm and 3 mm from the working length. All specimens were fixed, decalcified, and horizontally sectioned at the 1-mm and 3-mm marks. All specimens were stained, randomized, and examined via light microscopy at X100 magnification. Digital photographs were acquired and the amount of residual debris within the canal was calculated as a percentage of the canal lumen. The results revealed no statistically significant differences in amount of remaining debris between groups 3 mm from the working length. However, root canals irrigated with the EndoVac system exhibited significantly less debris 1 mm from the working length when compared to root canals irrigated with the ProRinse 30-gauge side-vented, closed-end irrigation needle.

In 2008 Hocket et al.[292] compared the antimicrobial efficacy of the EndoVac system compared to standard needle irrigation of preshaped root canals. Fifty-four mandibular molars were decoronated and the mesial canals were instrumented with Profile nickel-titanium orifice openers and Gates-Glidden drills. Teeth were then randomly divided into four groups of twelve teeth. Group one was instrumented with the Lightspeed LSX™ nickel-titanium rotary system to create nontapered preparations that were irrigated with the EndoVac system. Group two was also instrumented the same as group one, but irrigated with a traditional irrigation technique. Group three was instrumented with ProTaper nickel-titanium rotary files to create tapered preparations that were irrigated with the EndoVac system. Group four was instrumented that same as

group three but irrigated with a traditional irrigation technique. A positive and negative control were submitted to scanning electron microscopy to visualize presence and/or pattern of bacterial colonization. The nontapered Lightspeed LSX™ preparations were instrumented to an apical diameter of size #45. The tapered ProTaper preparations were instrumented to an apical diameter of size #35. Irrigation in all groups was initially performed with positive-pressure irrigation delivering 3.0 ml of 6.0-percent sodium hypochlorite followed by 1.5 ml of 17-percent EDTA, and 3.0 ml of 6.0-percent sodium hypochlorite. All teeth were then placed an ultrasonic bath of 17-percent EDTA for five minutes, followed by 6.0-percent sodium hypochlorite for five minutes. Teeth were dried, sterilized, and inoculated with *Enterococcus faecalis* under anaerobic conditions for 30 days. The access openings of all teeth were sealed with Cavit and the apical foramina were sealed with hot glue. External tooth surfaces were disinfected. Cavit was removed and root canals were rinsed with sterile saline and dried with sterile paper points. Bacterial samples and dentinal shavings were collected from all root canals. Groups two and three were irrigated with a 30-gauge Max-I-Probe side-vented, closed-end irrigation needle. The needle was progressed to a level 1.5 mm from the working length and irrigation solution was delivered. Initially 6.0-percent sodium hypochlorite was delivered for two minutes, followed by 17-percent EDTA for one minute, and again with 6.0-percent sodium hypochlorite for two minutes. Groups one and four were irrigated with the EndoVac system according to manufacturer's instructions. Macroirrigation of each can took place for 30 seconds with 6.0-percent sodium hypochlorite. The MacroCannula was moved up and down from binding point to immediately apical to the orifice of the canal. Three cycles of microirrigation took place

with 6.0-percent sodium hypochlorite for 30 seconds, followed by 17-percent EDTA for 30 seconds, and again with 6.0-percent sodium hypochlorite for 30 seconds. During this process, the MicroCannula was progressed to working length for six seconds, retracted approximately 2 mm for six seconds, progressed to working length for six seconds, and so on for the 30-second period. Irrigation solution was left undisturbed in the root canal for 30 seconds at the end of each cycle. The MicroCannula was then progressed to working length and used to evacuate irrigation solution from the canal. All canals were flushed with neutralizing solutions, dried. Bacterial samples and dentinal shavings were collected from all root canals, cultured, and incubated. The results revealed the presence of dense bacterial colonies suggestive of biofilm along the walls of all positive control teeth. All negative controls rendered negative cultures. There was no significant difference in cultivatable bacteria in irrigated root canals instrumented to a size #35 and #45. When twenty four root canals were irrigated with a 30-gauge Max-I-Probe side-vented, closed-end irrigation needle, 16 teeth rendered positive cultures. Negative cultures were acquired in all root canals irrigated with the EndoVac system, which was significantly better than root canals irrigated with a 30-gauge Max-I-Probe side-vented, closed-end irrigation needle.

In 2009 Brito et al.[294] compared the effectiveness of the EndoVac system, the EndoActivator, and conventional syringe and needle irrigation techniques in reducing *Enterococcus faecalis* within the root canal system. Seventy single-rooted canines were accessed. A standardized instrumentation technique was implemented using K-type files to prepare the apical foramen up to a size #25 and to irrigate with running water. Apical foramina were sealed with epoxy resin prior to mounting in blocks made of silicon

impression material. All specimens were sterilized via autoclave, inoculated with *Enterococcus faecalis,* and incubated for seven days. Sixty-six teeth were chosen for experimentation while four controls were submitted to scanning electron microscopy to evaluate pattern of bacterial colonization. Teeth were randomly divided into three groups of twenty dependent on irrigation method implemented. Six teeth were chosen as controls. All experimental root canals were sampled prior to instrumentation and irrigation. These samples were incubated, and colony-forming units (CFU) were counted. Group one was irrigated with a 30-gauge NaviTip needle placed 3 mm from the working length. Group two was also irrigated with a 30-gauge NaviTip needle placed 3 mm from the working length but with the adjunct of the EndoActivator. Group three was irrigated with the EndoVac system. Positive control teeth were irrigated a 30-gauge NaviTip needle placed 3 mm from the working length but using saline solution. The coronal and middle aspects of all root canals were prepared with a LA Axxess bur #35 followed by ProTaper nickel titanium rotary files to a size of #40 (F4) at the working length. Group one was irrigated with 2.5-percent sodium hypochlorite before instrumentation and between file transitions. Final irrigation consisted of 2.5-percent sodium hypochlorite, followed by 17-percent EDTA, and again with 2.5-percent sodium hypochlorite. Group two was irrigated with the same delivery technique, order of solutions, and volume of solutions. The EndoActivator was used with the blue tip size #35 with 0.04 taper placed 2 mm from working length at 10,000 cycles per minute for one minute after delivery of 17-percent EDTA and 2.5-percent sodium hypochlorite. Group three was irrigated with 2.5-percent sodium hypochlorite before instrumentation and between each file transition with the Master Delivery Tip. After instrumentation was

complete, 2.5-percent sodium hypochlorite was delivered via Master Delivery Tip with the adjunct of the MacroCannula abiding by manufacturer's recommendations. The canals were then irrigated with 2.5-percent sodium hypochlorite, followed by 17-percent EDTA, and again with 2.5-percent sodium hypochlorite. However, the MicroCannula replaced the MacroCannula during irrigation. The total volume of irrigation solution delivered in group one and two was 20 ml as compared to 43 ml in group three. Neutralizing solution and saline was introduced into all root canals. Bacterial samples were acquired and incubated. Colony-forming units (CFU) were counted and compared to those acquired before instrumentation and irrigation of root canals. All of the positive controls revealed root canal walls densely colonized by *Enterococcus faecalis* and positive cultures. All experimental irrigation groups yielded root canal walls of statistically less colony forming units of *Enterococcus faecalis* as compared to root canal walls irrigated with saline. All irrigation methods were effective in the reduction of *Enterococcus faecalis* but there were no statistically significant differences between groups.

In 2009 Townsend and Maki[295] compared efficacy of mechanical bacterial removal from plastic simulated root canals irrigated with the EndoVac, MiniEndo II (ultrasonic), Micromega 1500 (sonic), EndoActivator (sonic), F-file, and 28-gauge Max-I-Probe side-vented, closed-end needle. All simulated canals were curved approximately 30-degrees. Standardized instrumentation took place with a crown-down technique using Race nickel-titanium rotary files. The coronal and middle aspects were instrumented with a size #35 with 0.08 taper followed by size #40 with 0.08 taper. The master apical file was size #35 with 0.06 taper. Sterile water was flushed through all instrumented

canals which were dried by paper points prior to autoclave sterilization. Six blocks used as controls were filled with brain-heart infusion (BHI) broth. Thirty six blocks were inoculated with *Enterococcus faecalis* and incubated aerobically for seven days. The blocks were randomly assigned to groups of six. Group one (control) was irrigated with 6 ml of sterile water with a 28-gauge Max-I-Probe side-vented, closed-end needle positioned 2 mm from the apex. Group two was irrigated with the MiniEndo II ultrasonic unit for 30 seconds on low at 2 mm short of the apex. Short 2 mm to 3 mm cyclic axial motions were carried out for 30 seconds. Group three was irrigated with 6 ml of sterile water with a 28-gauge Max-I-Probe side-vented, closed-end needle positioned 2 mm from the apex. Group four was irrigated with the EndoVac system abiding by manufacturers instructions. Group five was irrigated with the EndoActivator at its highest speed. The size 15 tip of 0.02 taper was positioned 2 mm from the apex. Short 2 mm to 3 mm cyclic axial motions were carried out for 30 seconds. Group six was irrigated by setting the F-file to 900 rpm and placing the tip at length. It was moved in short circumferential 2-mm to 3-mm cyclic axial motions. Group seven was irrigated with the Micromega 1500 sonic handpiece positioned 2 mm from the apex. Short 2-mm to 3-mm cyclic axial motions were carried out for 30 seconds. Group one (MiniEndo II ultrasonic), group five (EndoActivator), group six (F-file), and group seven (Micromega 1500 sonic) were irrigated with 3 ml of sterile water before agitation and with 3 ml of sterile water after agitation. All canals were dried and filled with 0.1-percent crystal violet to stain remaining bacteria. Sterile water was then used to flush canals of excess crystal violet. The crystal violet was extracted using a detergent and measured with a spectrophotometer. Experimentation was repeated three times. The results revealed no

statistically significant difference between group one (MiniEndo II ultrasonic), group five (EndoActivator), group six (F-file), and group seven (Micromega 1500 sonic) in their ability to remove bacteria from a plastic simulated root canal. Irrigation with the adjunct of the MiniEndo II ultrasonic unit was significantly more effective in removing intracanal bacteria when compared to the EndoVac system and the 28-gauge Max-I-Probe side-vented, closed-end needle.

In 2009 Desai and Himel[291] evaluated the safety of various intracanal irrigation systems by the relative amount of apical extrusion of irrigation solution. Twenty-two extracted single-rooted maxillary central and lateral incisors were used in all six treatment groups. A standardized instrumentation technique was implemented using EndoSequence™ to a master apical file size of #50. A micro capillary tip was used to deliver 6.0-percent sodium hypochlorite to all roots visually eradicating all organic tissue. A collection vial was weighed, and all teeth were mounted so that with apices resided in the collection vial. The neck of the coronal aspect of the teeth were mounted and sealed in the lid of the collection vial with composite resins. A programmable precision syringe pump was used to deliver a precise rate of room temperature water to root canals in all irrigation groups except the Rinsendo group. Group one was irrigated with the EndoVac Master Delivery Tip (MDT) and the MicroCannula, which was progressed to full working length. Group two was irrigated with EndoVac Master Delivery Tip (MDT) and the MacroCannula which was progressed apically until the diameter of the canal limited its advancement. Group three was irrigated with the EndoActivator placed within 2 mm of the working length while moving in an up and down motion. Irrigation solution was delivered into the pulp chamber with an irrigation needle. Group four was irrigated with

a 30-gauge Max-I-Probe placed 2 mm short of the working length without binding and moving in an up and down motion. Group five was irrigated with via ultrasonic needle irrigation using a 25-gauge, beveled ultrasonic needle that was placed short of binding point and moved in an up and down motion during irrigation. Group six was irrigated with irrigated with the Rinsendo system at 45-PSI using a 3.5-ml syringe with cannula. Water was delivered into the coronal third of the canal without binding the cannula and moving it in an up and down motion during irrigation. The volume of irrigation delivered via the precision syringe pump was recorded. The collection vial was weighed and recorded. This value was compared to pre-test weights to determine the volume of irrigation solution apically extruded. The EndoVac MicroCannula (group one) and EndoVac MacroCannula (group two) relied on apical negative pressure, and were the only groups that did not extrude irrigation solution into the collection vial. The EndoActivator (group three) apically extruded significantly less irrigation solution compared to Max-I-Probe (group four), ultrasonic needle irrigation (group five) and Rinsendo (group six). There were no statistically significant differences in volume of irrigation solution apically extruded by the Max-I-Probe (group four), ultrasonic needle (group five) and Rinsendo (group six). The EndoVac system did not extrude any irrigation solution apically. Despite the "safety tip" of the side-vented, closed-end Max-I-Probe irrigation needle, it still extruded a significant amount of irrigation solution beyond the apex of root canals during irrigation.

In 2010 Brunson et al.[296] determined the effect of apical preparation size and preparation taper on the volume of irrigation solution delivered to the working length of root canals irrigated with the EndoVac system. Forty extracted, single-rooted human

teeth were decoronated. Root ends were dried and sealed with glue. Teeth were separated into two groups of twenty comprising two phases of experimentation. Group one was instrumented with K3 nickel-titanium rotary files with 0.06 taper to apical preparation sizes of 30, 35, 40, and 45 using a crown down technique. Between file transitions, all canals were irrigated with 1 ml of 6.0-percent sodium hypochlorite using the Master Delivery Tip and MacroCannula of the EndoVac system. After instrumentation was complete, the canals were irrigated with the 6.0-percent sodium hypochlorite for 30 seconds using the Master Delivery Tip and MicroCannula of the EndoVac system. Irrigation solution recovered at working length during this time period was measured via a custom recovery device. The results revealed the largest increase in irrigation solution volume delivered to the working length occurred when the apical size of the preparation was increased from #35 to a size #40. Based on these findings, in the second phase of experimentation the twenty root canals of group two were instrumented to an apical preparation size of #40. Canals were instrumented sequentially to preparation tapers of 0.02, 0.04, and 0.06 with K3 nickel-titanium rotary instruments and 0.08 taper with a ProFile GT nickel titanium rotary instrument. Between file transitions, all canals were irrigated with 1 ml of 6.0-percent sodium hypochlorite using the Master Delivery Tip and MacroCannula of the EndoVac system. After instrumentation was complete, the canals were irrigated with the 6.0-percent sodium hypochlorite for 30 seconds using the Master Delivery Tip and MicroCannula of the EndoVac system. Irrigation solution recovered at working length during this time period was measured via a custom recovery device. The results of phase one revealed the largest increase in irrigation solution volume delivered to the working length occurred when the apical size

of the preparation was increased from #35 to a size #40. An increase of approximately 44 percent in mean irrigation volume was observed. When the apical preparation diameter was increased from size #40 to size #45, the mean volume of irrigation solution increased by only 4.0 percent. The results of phase two revealed the largest increase in irrigation solution volume delivered to the working length occurred when the taper of the preparation was increased from 0.02 to 0.04. An increase of approximately 74 percent in mean irrigation volume was observed. When the taper of the preparation was increased from 0.04 to 0.06, the mean irrigation solution volume increased by only 5.4 percent. When the taper of the preparation was increased from 0.06 to 0.08, the mean irrigation solution volume increased by only 2.4 percent. The authors concluded that when using the EndoVac system, apical preparation to size #40 with a taper of 0.04 maximizes the volume of irrigation solution delivered to working length in conservation of tooth structure.

In 2010 Shin et al.[46] published a study similar to that of Nielsen and Baumgartner,[44] which compared the efficacy of the EndoVac system to standard needle irrigation in the debridement of root canals. However, in addition, this study also used a 30-gauge and 24-gauge needle and examined the effect of various apical sizes on debridement efficacy of the compared techniques. Sixty-nine extracted anterior teeth were decoronated and randomly divided into three experimental groups. Six teeth were not irrigated and were used as positive controls. Group one was irrigated with a 24-gauge needle, group two was irrigated with a 30-gauge needle and group three was irrigated with the EndoVac system. Each of these groups was divided into three subgroups. Subgroup A was prepared to a master apical file #25, subgroup B was prepared to master

apical file #40, and subgroup C was prepared to master apical file #60. Gates Glidden drills were used to coronallly flare the coronal aspect of all root canals. Working length was established 1 mm from working length with a K-type file of size #15. All teeth were placed in a paper cup filled with polyvinylsiloxane (PVS) impression material. All root canals were instrumented with ProFile nickel-titanium rotary files. Root canals of subgroup C were also instrumented with Lightspeed to establish a master apical file size of #60. During instrumentation, 1 ml of 6.0-percent sodium hypochlorite was delivered to the root canal system between file transitions. Final irrigation consisted of the delivery of 5 ml of 17-percent EDTA followed by 1 ml of 6.0-percent sodium hypochlorite. Apical patency was maintained with a K-type file of size #10. In group one and group two the irrigation needle was placed 2 mm short of the working length and moved coronally and apically while irrigation solution was being delivered. Teeth were removed from impression material. A scalpel was used to mark the external root surface 1.5 mm and 3.5 mm from the apical foramen. All teeth were fixed and decalcified. A microtome was used to horizontally section teeth at the 1.5 mm and 3.5-mm levels. Sections were stained and visualized at X100 under light microscopy. Digital photographs were acquired and computer analysis was used to calculate the amount of debris, in pixels, remaining in the root canal space. Residual debris was calculated as a percentage of total root canal lumen area. During irrigation in group three, the MacroCannula or MicroCannula of the EndoVac system was progressed to working length or apical binding point. The root canals irrigated with the 30-gauge needle exhibited significantly less residual debris at the 1.5-mm and 3.5-mm levels as compared to those irrigated with the 24-gauge needle. The root canals irrigated with the EndoVac

system exhibited significantly less remaining debris at the 1.5-mm and 3.5-mm levels as compared to root canals irrigated with standard 24-gauge or 30-gauge needle. When the EndoVac system was used there was significantly less remaining debris within the root canal at the 1.5-mm and 3.5-mm levels when the master apical file was increased from size #25, to #40, and to #60. The root canals instrumented to a master apical file size of #60 exhibited significantly less remaining debris at the 1.5-mm and 3.5-mm levels as compared to root canals instrumented to a master apical file size #25 or #40. than The authors concluded that the root canals irrigated with the EndoVac system were more effectively debrided at both levels. The authors concluded that the EndoVac yielded root canals with less residual debris than conventional 24-gauge and 30-gauge needle irrigation method. Increasing the size of root canal apical preparations increased the debridement efficacy of the EndoVac system.

SMEAR LAYER

Smear layer is defined by the American Association of Endodontists as a surface film of organic and inorganic debris retained on dentin and other surfaces after instrumentation with either rotary instruments or endodontic files.[7] This amorphous, irregular layer coating the root canal wall consists of dentin particles ("mud"), remnants of odontoblastic processes, remnants of vital or necrotic pulp tissue, bacterial components, retained irrigation solution, and microorganisms that accumulated during cleaning and shaping of the root canal system.[7, 192, 297, 298] Specifically, when root canals of teeth with a preoperative diagnosis of necrosis are instrumented, the smear layer may be largely contaminated by bacteria and their metabolic byproducts.[3] The relatively thin smear ranges from one to five microns in thickness, and is comprised of two separate

layers. The superficial layer is loosely adherent to the underlying deep layer, which is intimately attached to dentin of the root canal wall and extends into dentinal tubules in varying distances to form occluding plugs.[297, 299] The cross sectional design of rotary instruments used during cleaning and shaping has been shown to affect the appearance and structure of the smear layer created. Instruments with more active blades tend to shear dentin during cutting producing a thin superficial layer of smear. The more passive, U-shaped blades tend to burnish during instrumentation, which creates a thicker smear layer that penetrates deeper into dentinal tubules.[300, 301]

Smear layer is commonly removed from the root canal wall by chelating agents such as ethylenediaminetetraacetic acid (EDTA), citric acid, and tetracycline.[1-3, 192] A solution called BioPure™ MTAD (DENTSPLY Tulsa Dental Specialties) has also been recommended for smear layer removal, and consists of a mixture of the chelating agents tetracycline (doxycycline) and citric acid as well as a detergent called Tween-80 with surfactant properties.[302, 303] Chelating agents are chemical that bind to and inactivate specific metal ions to form soluble complexes. In the root canal system, chelating agents binds to calcium ions of hydroxyapatite leading to dissolution of the inorganic component of dentin.[194] The resultant demineralization process results in removal of smear layer and enlargement of dentinal tubules.[259, 260] A surfactant lowers the surface tension of a liquid, which may improve access and flow of solution into areas of impeded access, such as the apical extent of narrow root canals.[268, 271, 272]

Controversy has historically existed in the endodontic literature involving appropriate management of smear layer reaming on the root canal wall after instrumentation, and there is no consensus on whether or not it should be removed from

the prior to obturation.[3, 146, 192, 298] Drake[304] showed that the smear layer produced during instrumentation of root canal walls created a barrier that blocked bacteria from entering into dentinal tubules, preventing their colonization. Other authors have suggested that this barrier might also block irrigation solution from penetrating into the dentinal tubules.[192] Orstavik and Haapasalo showed that the presence of smear layer delayed the action of irrigation solutions and intracanal medicaments.[32]

Despite the controversy, today the majority of research-based evidence supports the removal of smear layer from root canal walls prior to obturation.[192, 305, 306] Obturation materials have been shown to exhibit enhanced adaptation to root canal walls devoid of smear layer.[307, 308] In addition, multiple sealers have been shown to more effectively adhere to dentin and penetrate to varying depths within dentinal tubules.[307-311] Thus, coronal and apical leakage of obturated root canals has been shown to be reduced with the removal of smear layer from the root canal wall.[305, 306, 312, 313] If the smear layer is not removed and leakage does occur, the smear layer may slowly disintegrate, furthering discontinuity of the interface between obturation and root canal wall, which could facilitate even more leakage.[3, 313] Also, the organic component of this residual smear layer may provide substrate for bacterial growth. Since the smear layer originally retained during instrumentation may have created a barrier preventing effective disinfection, viable bacteria may remain in the dentinal tubules.[3] These bacteria in addition to those which entered via increased microleakage may produce acid and enzymes which further the disintegration of the smear layer, leading to increased leakage and bacterial colonization.[3, 314] In addition, the smear layer itself often consists of residual bacteria or microbes not removed during instrumentation and irrigation.[192, 297, 298]

The primary goals of endodontic therapy are directed towards cleaning, shaping disinfecting, and hermetically sealing the root canal system.[145, 192] Removing the smear layer with appropriate chelating irrigations solutions helps facilitate these objectives, and should be implemented into endodontic therapy[192, 306]

EVALUATION OF POST-OPERATIVE ROOT CANAL CLEANLINESS

Clinically, probably the most relevant method of evaluation of root canal cleanliness involves the assessment of bacteria reduction and tissue removal. However these are also the most difficult criteria to assess. Instead, root canal debridement efficacy is often evaluated, with various methodologies proposed. Unfortunately, all methods possess their own set of shortcoming, and are unable to consistently provide accurate quantification of relative amounts of residual debris and smear layer remaining in the root canal system. Two of the most commonly advocated techniques consist of horizontally or longitudinally sectioning extracted teeth and evaluating sections histologically or under a scanning electron microscope.[30, 44, 46, 254, 255, 257] When teeth are sectioned horizontally the residual pulpal tissue, debris, and predentine can be stained. The amount of stained material can be quantitatively measured.[30, 44, 315] Horizontal sections allow for excellent examination of recesses and isthmuses. Unfortunately, during the process of sectioning loose debris within the canal lumen may be lost or dust from the saw blades may contaminate the root canal system. Prevention of contamination during the sectioning process is imperative and may be facilitated by the placement of a gutta-percha cone or paper point in the root canal prior to sectioning.[30]

Longitudinal sectioning of extracted roots provides a means for virtually complete evaluation of both halves of the entire main root canal. However, isthmuses and lateral

recesses are difficult to visualize and examine. Also, sectioning of a curved root is a technically difficult task. Several authors have recommended to initially section root segments horizontally prior to longitudinally sectioning.[30, 316] In 2010, Jiang[317] described an innovative method to reduce or eliminate the risk of introduced debris during sectioning of extracted teeth. Teeth were embedded into self-curing resin, and sectioned longitudinally with a microtome. Sandpaper was used to abrade the canal-side of the freshly sectioned root halves for ease of reapproximation. The two halves were then reassembled by inserting four self-tapping bolts through holes drilled through the resin blocks. A customized ultrasonic tip was used to implement a standard groove of 4 mm in length, 0.5 mm in depth, and 0.2-mm wide into one half of each root canal 2 mm to 6 mm from the working length. These simulated oval aspects of the apical root canal were filled with dentin debris and sodium hypochlorite mixture to simulate the dentin debris accumulation canal extensions prior to instrumentation. This method allowed for a standardized root canal space and ability to quantify the amount of dentin debris present in the root canal before irrigation. When root halves were separated and evaluated via stereomicroscope, the reliability of evaluation of dentin debris removal after instrumentation and irrigation was enhanced.

According to Hulsmann[30] analyzing root segments via scanning electron microscopy (SEM) is the standard technique for assessing the cleanliness of root canals after instrumentation and irrigation. Scanning electron microscopy (SEM) is a topographic technique of analyzing surfaces of solid objects. A beam of finely focused electrons of relatively low energy are scanned across a sample, which stimulates emission of high-energy backscattered electrons and low-energy secondary electrons from the

surface of the specimen. The backscattered electrons are analyzed to produce a physical image of the surface of the specimen of high topographical detail. When the electron beam of the SEM is focused on the specimen the surface becomes charged. In order to overcome charging of the surface the specimen must be rendered electrically conducting. Specimen conductivity allows for acquisition of a sharp image and is usually accomplished by evaporating a film of metal alloy in a vacuum. In this process of sputter-coating, the specimen is usually covered with a thin layer of gold and/or palladium.[318-321]

SEM photographs of root canal segments are often scored according to the relative amount of residual debris and/or smear layer remaining after instrumentation and irrigation to determine root canal cleanliness. Debris can be defined as dentin chips, tissue remnants and particles loosely attached to wall of the root canal system.[30] The American Association of Endodontists defines smear layer as a surface film of debris retained on dentine or other surfaces after instrumentation with either rotary instruments or endodontic files; consists of dentine particles, remnants of vital or necrotic pulp tissue, bacterial components and retained irrigation solution.[7] Many different scoring systems have been proposed. Some systems consist of pre-defined scores with a wide variation in the description and number of scores, while other systems are completely descriptive in nature [6, 30, 35, 193, 251, 254-257, 265, 266, 273, 297, 299, 300, 322].

In 1997 Hulsmann et al.[6] evaluated the cleanliness of root canal walls after preparation with various automated devices using scanning electron microscopy. Relative amount of debris remaining on the root canal wall was evaluated under X200 magnification using the following scores:

1) Clean root canal wall, only few small debris particles.
2) Few small agglomerations of debris.
3) Many agglomerations of debris covering less than 50 percent of the root canal wall.
4) More than 50 percent of the root canal wall covered by debris.
5) Complete or nearly complete root canal wall covered by debris.

Relative amount of smear layer remaining on the root canal wall was evaluated at X100 magnification using the following scores:

1) No smear layer, dentinal tubuli open.
2) Small amount of smear layer, some dentinal tubuli open.
3) Homogenous smear layer covering the root canal wall, only few dentinal tubuli open.
4) Complete root canal wall covered by a homogenous smear layer, no open dentinal tubuli.
5) Heavy, nonhomogenous smear layer covering the complete root canal wall.

In 2006, Al-Hadlaq et al.[322] evaluated the efficacy of NaviTip FX in removing root canal debris during nonsurgical endodontic therapy via scanning electron microscopy. Relative amount of debris remaining on the root canal wall was evaluated under X200 magnification using the following scores:

1) Clean root canal, only few small debris particles.
2) Few small isles of debris covering less than 25 percent of the root canal wall.
3) Many accumulations of debris covering more than 25 percent but less than 50 percent of the root canal wall.

4) More than 50 percent of the root canal wall covered by debris.

Various magnifications used under scanning electron microscopy have been proposed in the literature.[6, 30, 35, 193, 251, 254-257, 265, 266, 273, 297, 299, 300, 322] When higher magnifications are chosen, only small areas of the root canal can be observed requiring the SEM operator to subjectively choose an area to evaluate. Also, root canal cleanliness is usually superior in the coronal portion of the root canal as compared to the middle and apical aspects. Therefore, an examination procedure specifying the results for different sections of the root canal system is recommended.[30]

MATERIALS AND METHODS

SAMPLE SIZE

Multiple extracted, single-rooted, human canines were chosen from the Oral Health Department under IUPUI/Clarian IRB #0306-64. Teeth were scrupulously evaluated, randomly choosing a total of sixty select samples for subsequent experimentation (FIGURE 1).

SELECTION AND CLEANING

Inclusion Criteria

Only teeth exhibiting minimal restoration which accounted for less than one half of coronal tooth structure were chosen. Teeth must have exhibited radicular curvature less than thirty degrees as determined with protractor. Only teeth with visually "closed" apices were chosen. All teeth were then radiographed via Planmeca Dixi at 70 kVp, 8 mA, and 0.01s confirming relatively normal anatomy, absence of canal obliterating pulpal calcifications, and canal curvature of less than thirty degrees. Curvature of canal was quantified using the Schneider[323] technique. Teeth were radiographed from facial-lingual and mesial-distal directions and angle was measured at point in which canal began to deviate from long axis of the tooth (FIGURE 2). Medical Imaging Picture Archive Communication System (MiPACS™) was utilized to determine angle calculations (FIGURE 3).

Exclusion Criteria

Teeth exhibiting coronal restorations comprising more than one half of coronal tooth structure, including all onlays and crowns, as well as any teeth with radicular restorations were excluded from experimentation. Teeth in which apical foramen allowed insertion of a new Lexicon (DENTSPLY-Tulsa, Tulsa, OK) #30 K-type file were excluded from the study (FIGURE 4). Radiographed teeth that exhibited canals not able to be followed from chamber to apex due to calcification or canals with curvature greater than thirty degrees were excluded from the study (FIGURE 3). Again, canal curvature was quantified by the Schneider Technique[323] via the angle calculation tool integrated within the MiPACS™ software (FIGURE 3).

SPECIMEN PREPARATION

Major extraradicular accretions were removed with universal periodontal scalers (FIGURE 5). All teeth were saturated in 6.0-percent sodium hypochlorite (The Clorox Company, Oakland, CA) for two weeks prior to initiating experimentation. The sodium hypochlorite solution was changed every two to three days during the two-week soaking period. All teeth were then decoronated. A diamond coated separating disc loaded in a Dremel rotary tool was utilized to place horizontal, full-section, coronal cuts parallel to most superior aspects of cement-enamel junction (FIGURE 6). Teeth were then soaked in 0.9-percent normal saline solution between laboratory sessions until initial hand instrumentation initiated (FIGURE 7).

TOOTH PREPARATION

Initial Hand Instrumentation

Graduated 12-ml Monoject syringes equipped with 30-gauge ProRinse (DENTSPLY, Tulsa, OK) (FIGURE 8), side-vented, closed-end needles were used to deliver 1 ml of 6.0-percent sodium hypochlorite (FIGURE 9). The ProRinse needle possesses a 1-mm side-port positioned approximately 1 mm from the ball tip prohibiting delivery of solution from its terminal extension (FIGURE 10). A needle gauge of 30 coincides with a diameter of 0.305 mm.[324] Constant and maximum force was attempted to be placed on the Monoject plunger during expression of sodium hypochlorite.

All teeth were then instrumented under approximately eight times magnification with a Global Surgical™ Microscope (Global Surgical™, St. Louis, MO) using Lexicon (DENTSPLY-Tulsa, Tulsa, OK) K-type files in sequential order from size #6, #8, to #10. Each file was passed approximately 1 mm to 2 mm beyond apical foramina of all teeth to ensure apical patency (FIGURE 11). The file was then retracted to level of apical foramen as visualized at eight times magnification (FIGURE 12). One mm was subtracted from this measurement to provide an ideal working length approximating anticipated level of apical constriction (FIGURE 13).[139-143] File measurements were determined with the adjunct of rubber stoppers placed and the ruler from the Endoring I (Almore International, Inc., Portland OR). The same Endoring I was utilized throughout experimentation. Mesial or distal root surfaces of all teeth were then labeled with a permanent, black, Sharpie (Newell Rubbermaid™, Atlanta, GA) marking pen indicating determined working length. All teeth were placed in groups according to these lengths. Roots exhibiting a working length less than 14 mm or more than 17 mm were excluded

from the study. All canals were then subsequently instrumented with Lexicon size #15 and #20 K-type files to previously determined working length using the balanced force technique (FIGURE 14).[170] All canals were recapitulated with Lexicon size #10 K-type files, approximately 1 mm beyond apices to maintain apical patency and loosen intracanal debris for subsequent irrigation and evacuation. The ProRinse needle of the Monoject syringe was taken to a point of apical binding or working length, choosing the shorter of the two, and retracting 1 mm. The syringe was then progressed and retracted in pumping motion over a length of approximately 5 mm careful not to extend beyond one mm short of working length. One ml of 6.0-percent sodium hypochlorite was expressed from syringe during this pumping motion. Constant and maximum force was attempted to be placed on the Monoject plunger during expression of sodium hypochlorite. In the event that the needle ever became clogged or flow rate was notably decreased, the syringe and needle were replaced.

The outer aspects of root apices were wiped with dry gauze square to remove obvious moisture and/or debris. Teeth were then sealed and stored between laboratory sessions in biopsy containers with sterile gauze squares dampened with 0.9-percent normal saline.

Creation of a "Closed System"

Teeth were removed from biopsy containers and spread out onto paper to air-dry for approximately ten minutes. Corning sticky wax (Corning Rubber Co., Inc., Ronkonkoma, NY) was heated with open flame from Blazer microtorch (Blazer Products, Inc., Farmingdale, NY) and indirectly applied to apices of all roots (FIGURE 15). Kerr vinyl-polysiloxane adhesive (Kerr Corporation, Orange, CA) was applied to entire

exterior root surface of all teeth in order to facilitate a "closed system" within root canals (FIGURE 16). [44, 46, 256] Apices were visualized again under eight times magnification to assure that apices were occluded by wax and that entire aspect of root surfaces was covered with adhesive (FIGURE 17). The adhesive was allowed to harden for at least five minutes. Two-ml disposable test tubes were loaded with medium-body, Kerr Extrude vinyl-polysiloxane (VPS) impression material. Test tubes were filled approximately three mm inferior to rim, minimizing air bubbles and/or voids (FIGURE 18). Roots were then seated into the impression material of each test tubes leaving approximately 1 mm to 2 mm of coronal root structure visible (FIGURE 19). Impression material was manually adapted to coronal root structure. Test tubes were placed upright and held stationary in test tube rack for at least seven minutes. Confirmation of complete polymerization was performed by placing fingernail in impression material and noting no indentation on removal. Excess impression material was trimmed from coronal root structure with #15 scalpel blade mounted in Bard-Parker handle. Working lengths were recorded on convex surface of all test tubes with a permanent, black, Sharpie marking pen (FIGURE 20). Between laboratory sessions, all test tubes were stored in upright positions in a test tube rack with coinciding lids sealed into place (FIGURE 21).

Rotary Instrumentation

All canals were instrumented with the ProTaper (DENTSPLY-Tulsa, Tulsa, OK) nickel-titanium rotary file system according to manufacturer's recommendations (FIGURE 22). [176-178] Files were loaded into the Aseptico ITR Minihead (Aseptico, Inc., Woodinville, WA) 8:1 reduction contra-angle handpiece, which was driven by the Aseptico Endo ITR™ (DENTSPLY-Tulsa, Tulsa, OK) electric motor set at 300

revolutions per minute (FIGURE 23). The same contra-angle handpiece and motor were utilized throughout experimentation. File measurements were determined with the adjunct of rubber stoppers placed and the ruler from the Endoring I (Almore International, Inc., Portland OR). The same Endoring I was utilized throughout experimentation. Each ProTaper file was used five times before discarding. ProLube (DENTSPLY, Tulsa, Tulsa, OK) lubrication gel was applied to every rotary file prior to insertion into the root canal (FIGURE 24). After instrumentation with each file, 6.0-percent sodium hypochlorite was introduced into the root canal system. Six-percent sodium hypochlorite was delivered to all root canals between file transitions with the volume and method of delivery varying between experimental groups, as outlined in the next section.

All specimens remained upright in test-tube rack throughout all rotary instrumentation. ProTaper S1 and S2 (Tulsa Dental Products, Tulsa, OK) rotary files were progressed to working lengths in sequential order, using the recommended brushing motion on withdrawal (FIGURE 25). ProTaper F1, F2, F3, F4, and F5 (Tulsa Dental Products, Tulsa, OK) rotary files were progressed to working length in sequential order and quickly retracted with no brushing motion implemented on withdrawal (FIGURE 26).[176-178] A Lexicon size #50 K-type file was progressed to working length of all root canals to confirm apical stops (FIGURE 27). Those teeth in which an apical stop was not established were excluded from the study. All root canals were then recapitulated with a Lexicon #10 K-type file to level of apex to maintain patency and loosen intracanal debris for subsequent irrigation and evacuation (FIGURE 28). Test tube lids were again seated

into place to seal accessed roots from outside contaminants between laboratory sessions (FIGURE 21).

GROUP ASSIGNMENT

All samples were placed in a test-tube rack and visually examined (FIGURE 29). Any root that exhibited major asymmetry in outline, loss of hard structure, suspected fracture, adhesive or impression material approximating access opening, a canal with extreme asymmetry, or other anomaly that may have affected standardization of samples was excluded from experimentation (FIGURE 30). All acceptable samples were placed in a stainless steel instrument bin. The bin was rotated upside down approximately five times to randomize the samples (FIGURE 31). Without visualizing the samples, the test tubes were manually retrieved and placed in one of three groups. The first sample collected was placed into group one (control), the second sample placed in group two (EndoVac), the third sample placed in group three (Canal CleanMax), the fourth sample placed in group one (control), and so on until all 60 samples were grouped (FIGURE 32). The remaining samples were stored for use in the event that original samples needed to be excluded from the study.

Group one (control) consisted of 20 teeth and was irrigated and aspirated utilizing only a standard graduated 12-ml Monoject syringe with ProRinse 30-gauge side-vented, closed-end needle. Group two consisted of 20 teeth and was irrigated and aspirated utilizing the EndoVac, system strictly abiding by manufacturer's recommendations. Group three consisted of 20 teeth and was irrigated utilizing a standard graduated 12- ml Monoject syringe with a ProRinse 30-gauge side-vented, closed-end needle and the Canal CleanMax system, strictly abiding by manufacturer's recommendations.

IRRIGATION AND ASPIRATION

Pilot Study: Irrigation Solution Volume Determination

A pilot study was conducted in order to calculate standardized volumes of 6.0-percent sodium hypochlorite and 17-percent ethylenediaminetetraacetic acid to be delivered to root canals in each study group between file transitions and after final instrumentation. Since 1 ml of 6.0-percent sodium hypochlorite was utilized during hand instrumentation, this volume was used to determine the duration in which all study groups would deliver sodium hypochlorite between file transitions. A total of six, new, 12-ml, Monoject syringes equipped with six, new, ProRinse, 30-gauge, side-vented, closed-end needles were used. Constant and maximum force was attempted to be placed on the Monoject plunger during expression of 1 ml of sodium hypochlorite. The same online timer tool was utilized for all experimentation.[325] The average duration for expression of 1 ml of 6.0-percent sodium hypochlorite was approximately ten seconds. Thus, further calculation of volumes to be utilized between file transitions for each group was based on delivery of 6.0-percent sodium hypochlorite for ten seconds (FIGURE 33 and TABLE I)

Both manufacturers recommended irrigation regimens of 30 seconds following instrumentation.[47, 48, 50-54] Thus, the volumes of irrigation solutions to be delivered after irrigation were determined by calculating the average amount of sodium hypochlorite and 17-percent ethylenediaminetetraacetic acid delivered over thirty-second intervals. The same online timer tool was utilized for all experimentation.[325] The first three delivered 6.0-percent sodium hypochlorite, and the second three delivered 17-percent EDTA

(FIGURE 34). This same process was repeated using six, 12-ml Monoject, syringes equipped with the EndoVac Master Delivery Tip (MDT) (FIGURE 34). Constant and maximum force was attempted to be placed on the Monoject plunger during expression of irrigation solutions. The calculated mean volumes expressed over 30-second intervals for each group were delivered after all hand and rotary instrumentation was completed. For the EndoVac, values were also calculated for approximate volume of 6.0-percent sodium hypochlorite and 17-percent ethylenediaminetetraacetic acid to be expressed during the five, six-second intervals of the 30-second "microcycle." All calculated mean volumes for each solution and study group are outlined (FIGURE 33 and TABLE I.)

Group One (Control): Root Canal Preparation

Twenty, randomly selected teeth were irrigated utilizing only a standard 12- ml Monoject syringe with a ProRinse, 30-gauge, side-vented, closed-end needle (FIGURE 8). The ProRinse needle possesses 1-mm side-port positioned approximately 1 mm from the ball tip prohibiting delivery of solution from its terminal extension (FIGURE 10). A needle gauge of 30 coincides with a diameter of 0.305 mm.[324] In the event that the needle became clogged or flow rate was notably decreased, the syringe and needle were replaced.

One syringe was filled with 6.0-percent sodium hypochlorite while another syringe was filled with 17-percent EDTA. A yellow stopper was placed on the needle of the syringe containing sodium hypochlorite, and a red stopper was placed on the needle of the syringe filled with 17-percent EDTA (FIGURE 35). The needle of the syringe was taken to a point of apical binding or working length, with the shorter of the two chosen, at which point 1 mm was retracted. The needle of the syringe was then progressed and

retracted in a “pumping” motion over a length of approximately 5 mm, careful not to progress apical to 1 mm short of binding point/working length. Constant pressure was applied to the plunger of the syringe during irrigation delivery. Initially, 1 ml of 6.0-percent sodium hypochlorite was delivered to all root canals (FIGURE 36). This volume was chosen based on a pilot study prior to instrumentation. (FIGURE 33 and TABLE I). All specimens remained upright in test-tube rack throughout all irrigation.

After the final ProTaper F5 file was progressed to working length, the canals were again irrigated utilizing the same technique previously described. A Lexicon size #50 K-type file was progressed to working length of all root canals to confirm apical stops (FIGURE 27). Those teeth in which an apical stop was not established were excluded from the study. All root canals were then recapitulated with a Lexicon #10 K-type file to level of apex to maintain apical patency and loosen intracanal debris for subsequent irrigation and evacuation (FIGURE 28). The aforementioned process of irrigation was repeated, but this time using 3 ml of 6.0-percent sodium hypochlorite. This volume was determined from pilot study calculations of the average volume of 6.0-percent sodium hypochlorite delivered over 30-seconds. (FIGURE 33 and TABLE I).

In an attempt to remove the smear layer from root canal walls, 17-percent EDTA was expressed into canal system with the same irrigation technique previously described (FIGURE 37). As determined by pilot study, 2 ml of 17-percent EDTA was delivered (FIGURE 33 and TABLE I). The solution of EDTA remained undisturbed within the canal system for 60 seconds as timed by an online stopwatch.[266, 325-329] Solution was aspirated by pulling back on the plunger of the Monoject syringe while the needle was progressed to the working length. The plunger was retracted until no visible solution was

expressed into the syringe barrel. Six-percent sodium hypochlorite was again introduced into the root canal system with the same irrigation technique as previously described. As determined by pilot study, 3 ml of 6.0-percent sodium hypochlorite was delivered (FIGURE 33 and TABLE I). Solution was aspirated by pulling back on the plunger of the Monoject syringe while the needle was progressed to the working length. The plunger was retracted until no visible solution was expressed into the syringe barrel. All canals were then dried with five coarse paper points (DENTSPLY International, York, PA), allowing each point to sit at working length for three seconds prior to retraction from canal (FIGURE 38). Total volume of 6.0-percent sodium hypochlorite and 17-percent EDTA delivered during entire irrigation regimen was recorded (FIGURE 39 and TABLE II).

Group Two: Root Canal Preparation Irrigating with the EndoVac System

Twenty randomly selected teeth were irrigated with the EndoVac System abiding by the inventor/manufacturer's recommendations (FIGURE 40). A new refill kit was utilized on every root canal irrigated. All irrigation solutions were delivered with 12-ml Monoject syringes threaded with Master Delivery Tips (MDT) during and after instrumentation (FIGURE 41). The MDT consists of a plastic evacuation hood surrounding a stainless steel cannula, which extends approximately 2 mm to 3 mm beyond the hood. The cannula is made of 10-28 stainless steel with an inner lumen diameter of ten thousandths of an inch (0.254 mm) and an outer lumen diameter of twenty-eight thousandths of an inch (0.711 mm).[324] The plastic hood was attached via clear tubing to a "T-connector," which coupled to a large grey evacuation hose (FIGURE 41). All attachments were facilitated with Luer connectors. The evacuation hose was

connected to the high volume evacuation of the dental unit (FIGURE 41).[47-50] Prior to irrigation, the trap of the dental unit's suction system was replaced, and the high evacuation suction valve was fully opened (FIGURE 42).

Initially, the stainless steel cannula of the MDT was placed "just inside the access opening of the tooth" expressing 6.0-percent sodium hypochlorite with constant pressure "at an axial wall and never towards a pulp canal orifice (FIGURE 43).[47, 49] Constant pressure was applied to the plunger of the syringe until 4 ml of 6.0-percent sodium hypochlorite was delivered. This volume was determined from pilot study calculations of the average volume of 6.0-percent sodium hypochlorite delivered over 10-seconds. (FIGURE 33 and TABLE I). Excess irrigation solution delivered was simultaneously aspirated by the plastic hood of the MDT. Aspirated solution was evacuated through connected tubing from the negative pressure of the high volume evacuation system of the dental unit.[48-50]

The aforementioned process was repeated after each ProTaper rotary file transition. Once the final ProTaper F5 file was progressed to working length and the canals were irrigated, a Lexicon size #50 K-type file was progressed to working length of all root canals to confirm apical stops (FIGURE 27). Those teeth in which an apical stop was not established were excluded from the study. All root canals were then recapitulated with a Lexicon #10 K-type file to the level of the apex to maintain patency and loosen intracanal debris for subsequent irrigation and evacuation (FIGURE 28).

After all instrumentation was completed, irrigation was continued using the MDT with the adjunct of the MacroCannula. The MacroCannula is constructed of transparent blue polypropylene and fits into a titanium handpiece. The titanium handpiece was

coupled to a clear hose, which attached via Luer connector to the “T-connector” already linked to the MDT and grey evacuation hose (FIGURE 44). The MacroCannulas used were 25 mm in length, but are also available in 31-mm lengths. The outer lumen diameter of the MacroCannula is 0.55 mm, and the inner lumen diameter is 0.35 mm (FIGURE 45). The MacroCannula exhibits a 2.0-percent taper.[48-50]

The MacroCannula was marked with a permanent, black, Sharpie marking pen at appropriate working length (FIGURE 46). Measurements were determined with the adjunct of rubber stoppers placed and the ruler from the Endoring I. The same Endoring I was utilized throughout experimentation. The MacroCannula was progressed to a point of apical binding or working length, choosing the shorter of the two, and progressed and retracted in pumping motion from level of canal orifice to previously determined apical stop (FIGURE 47). During this motion, 12 ml of 6.0-percent sodium hypochlorite was simultaneously delivered and evacuated via 12-mililiter Monoject syringe equipped with the EndoVac MDT. This volume was determined from pilot study calculations of the average volume of 6.0-percent sodium hypochlorite delivered over 30-seconds (FIGURE 33 and TABLE I). The MacroCannula was then quickly removed from the canal followed by the MDT.[47-49, 325]

The remainder of the EndoVac irrigation regimen utilized the MDT with implementation of the MicroCannula (FIGURE 48). The MicroCannula is constructed of stainless steel and fits into a titanium fingerpiece (FIGURE 48). The titanium fingerpiece was coupled to a clear hose, which attached via Luer connector to the “T-connector” already linked to the MDT and grey evacuation hose (FIGURE 48). The MicroCannula is non-tapered and measures 0.32 mm in diameter (FIGURE 49). Twelve, radially

arranged holes, each measuring 0.10 mm in diameter are positioned between 0.2 and 0.7 mm from the MicroCannula's spherical, welded end (FIGURE 50). Each micro hole is smaller than the internal diameter of the MicroCannula. The MicroCannulas used were 25 mm in length, but are also available in 31-mm lengths.[47-49]

The MicroCannula was marked with a permanent, black, Sharpie marking pen at appropriate working length (FIGURE 51). Measurements were determined with the adjunct of rubber stoppers placed and the ruler from the Endoring I. The same Endoring I was utilized throughout experimentation. The small titanium fingerpiece was used to progress the MicroCannula to working length in the root canals. The MicroCannula was repositioned 2 mm up and down within the canal. During this motion, 12 ml of 6.0-percent sodium hypochlorite was simultaneously delivered and evacuated via a 12-mililiter Monoject syringe equipped with the EndoVac MDT (FIGURE 52). This volume was determined from pilot study calculations of the average volume of 6.0-percent sodium hypochlorite delivered over 30-seconds (FIGURE 33 and TABLE I). The precise placement and movements of the MicroCannula during the 30-second active irrigation period or "Microcycle" are outlined below.[47-49]

1) Time zero to six seconds (2.4 ml) at working length.
2) Time seven to 12 seconds (2.4 ml) at working length minus 2 mm.
3) Time 13 to 18 seconds (2.4 ml) at working length.
4) Time 19 to 24 seconds (2.4 ml) at working length minus 2 mm.
5) Time 25 to 30 seconds (2.4 ml) at working length.
6) Time 30 to 90 seconds-Passive wait period with no irrigation or manipulation.

The MicroCannula was again progressed to working length allowing suction to evacuate until no solution was visibly moving in the tubing system. In an attempt to remove the smear layer from root canal walls, 10 ml of 17-percent EDTA was introduced into all root canals via the same "Microcycle" previously outlined (FIGURE 53). This volume was determined from pilot study calculations of the average volume of 17-percent EDTA delivered over 30-seconds (FIGURE 33 and TABLE I). Finally, a third "Microcycle" was initiated, delivering 12 ml of 6.0-percent sodium hypochlorite as previously outlined (FIGURE 52). Excess solution was removed from canals by advancing the MicroCannula to working length and allowing suction to evacuate until no solution was visibly moving in the tubing system. No paper points were used in drying the root canal systems. Total volume of 6.0-percent sodium hypochlorite and 17-percent EDTA delivered during entire irrigation regimen was recorded (FIGURE 39 and TABLE II).[47-50]

Group Three: Root Canal Preparation Irrigating with the Canal CleanMax System

Twenty randomly selected teeth were irrigated utilizing a standard 12-ml Monoject syringe with a ProRinse, 30-gauge, side-vented, closed-end needle and the Canal CleanMax System, abiding by inventor/manufacturer's recommendations (FIGURE 8 and FIGURE 54).[51, 53, 54] The ProRinse needle possesses a 1-mm side-port positioned approximately 1 mm from the ball tip prohibiting delivery of solution from its terminal extension (FIGURE 10). A needle gauge of 30 coincides with a diameter of 0.305 mm.[324] In the event that the needle became clogged or flow rate was notably decreased, the syringe and needle were replaced.

The Canal CleanMax consists of an autoclavable stainless steel handpiece with detachable suction head that freely rotates 360-degrees (FIGURE 55). Disposable "insert tubes" are connected to the nozzle of the suction head and are inserted into the root canal system during irrigation (FIGURE 55). The handpiece attaches to the 2-hole or 4-hole turbine-hose connection of the dental unit (FIGURE 55). Compressed air from the dental unit drives the delivery of sterile water from three holes at the base of the suction head to the nozzle-insert tube interface (FIGURE 56), while simultaneously generating negative pressure within the insert tubes. The amount of water pressure delivered is dependent on the dental unit settings and the "power control ring" of the handpiece (FIGURE 57). This ring also controls the level of negative pressure created within the insert tubes. Fluid and debris from the root canal system is aspirated through the insert tubes and evacuated out the "exhaust vent" positioned on the front of the suction head (FIGURE 58). In our study, and clinically, the exhaust is collected by close approximation of the high evacuation suction tip.[51, 53, 54]

The insert tubes are constructed of polyethylene, measure 21 mm in length, and exhibit a standardized 0.04 taper. The outer lumen of the tubes is 0.6 mm in diameter, while the inner diameter is 0.35 mm (FIGURE 59). In the event that lumen of the tubes become clogged, the button on top of the handpiece is depressed (FIGURE 60), activating the "One-push cleaning system." When depressed, the button causes the negative pressure within the handpiece to be reversed to positive pressure. Compressed air from the dental unit then forces fluid and debris out of the exhaust vent and insert tubes. The Canal CleanMax system is also packaged with spare O-rings and a cleaning wire (FIGURE 61 and FIGURE 62). The O-rings are housed in the handpiece and

enhance the seal of the connection to the suction head (FIGURE 61). The flexible cleaning wire can be inserted into the nozzle or exhaust vent of the suction head for removal of foreign objects in the event of clogging or prior to sterilization (FIGURE 62).[51-54]

Prior to irrigation with the Canal CleanMax, the air pressure of the dental unit was calibrated via manufacturer's instructions. A standard high-speed handpiece was connected to the dental unit. The air pressure of the unit was adjusted via hex key until approximately 35 pounds per square inch was being constantly delivered (FIGURE 63). The high-speed handpiece was disconnected and replaced with the Canal CleanMax handpiece.[53] The knob controlling water flow from the dental unit was fully opened allowing for maximum production. Lastly, the "power control ring" of the Canal CleanMax handpiece was also fully opened so that maximum water flow was delivered and maximum negative pressure produced (FIGURE 57).

During rotary instrumentation, standard 12-ml Monoject syringes with ProRinse, 30-gauge, side-vented, closed-end needles were used for delivery of irrigation solutions, exactly mimicking methods of the control group (FIGURE 8). One syringe was filled with 6.0-percent sodium hypochlorite while another syringe was filled with 17-percent EDTA. A yellow stopper was placed on the needle of the syringe containing sodium hypochlorite, and a red stopper was placed on the needle of the syringe filled with 17-percent EDTA (FIGURE 35). The needle of the syringe was taken to a point of apical binding or working length, with the shorter of the two chosen, at which point 1 mm was retracted. The needle of the syringe was then progressed and retracted in a "pumping" motion over a length of approximately 5 mm, careful not to progress apical to 1 mm short

of binding point/working length. Constant pressure was applied to the plunger of the syringe during irrigation delivery. Initially, 1 ml of 6.0-percent sodium hypochlorite was delivered to all root canals (FIGURE 36). This volume was chosen based on a pilot study prior to instrumentation. (FIGURE 33 and TABLE I). All specimens remained upright in test-tube rack throughout all irrigation.

After the final ProTaper F5 file was progressed to working length, the canals were again irrigated utilizing the same technique previously described. A Lexicon size #50 K-type file was progressed to working length of all root canals to confirm apical stops (FIGURE 27). Those teeth in which an apical stop was not established were excluded from the study. All root canals were then recapitulated with a Lexicon #10 K-type file to level of apex to maintain apical patency and loosen intracanal debris for subsequent irrigation and evacuation (FIGURE 28). The aforementioned process of irrigation was repeated, but this time using 3 ml of 6.0-percent sodium hypochlorite. This volume was determined from pilot study calculations of the average volume of 6.0-percent sodium hypochlorite delivered over 30-seconds (FIGURE 33 and TABLE I). Further irrigation was performed with the adjunct of the Canal CleanMax.

The insert tubes of the Canal CleanMax were marked with a permanent, black, Sharpie marking pen at appropriate working lengths (FIGURE 64). Measurements were determined with the adjunct of rubber stoppers placed and the ruler from the Endoring I. The same Endoring I was utilized throughout experimentation. A new insert tube was utilized for every root canal irrigated.

The water delivery switch attached to the rheostat of the dental unit was turned "on." With a pool of sodium hypochlorite remaining within the access opening, the insert

tube attached to the suction head of the Canal CleanMax handpiece was inserted into the canal to a point of apical binding or working length, choosing the shorter of the two. The foot pedal of the rheostat was depressed (FIGURE 65). The insert tube was progressed and retracted in pumping motion from level of canal orifice to previously determined apical stop for thirty seconds. Time was calculated by placement of an analog clock in front of the operator and starting and stopping irrigation according to the second-hand (FIGURE 65). The water delivery switch attached to the rheostat of the dental unit was then turned "off." The insert tube was again progressed and retracted in pumping motion from level of canal orifice to previously determined apical stop until no moving solution was visible within the insert tubes or exiting the exhaust vent.

In an attempt to remove the smear layer from root canal walls, 17-percent EDTA was expressed into canal system with the same irrigation technique previously described with the standard 12-ml Monoject syringes with ProRinse, 30-gauge, side-vented, closed-end needles (FIGURE 37). As determined by pilot study, 2 ml of 17-percent EDTA was delivered (FIGURE 33 and TABLE I). The solution of EDTA remained undisturbed within the canal system for 60 seconds as timed by an online stopwatch.[266, 325-329] The water delivery switch attached to the rheostat of the dental unit was turned "on." With a pool of EDTA remaining within the access opening, the insert tube attached to the suction head of the Canal CleanMax handpiece was inserted into the canal to a point of apical binding or working length, choosing the shorter of the two. The foot pedal of the rheostat was depressed (FIGURE 65). The insert tube was progressed and retracted in pumping motion from level of canal orifice to previously determined apical stop for thirty seconds. Time was calculated by placement of the same analog clock in front of the

operator and starting and stopping irrigation according to the second-hand (FIGURE 65). The water delivery switch attached to the rheostat of the dental unit was then turned "off." The insert tube was again progressed and retracted in pumping motion from level of canal orifice to previously determined apical stop until no moving solution was visible within the insert tubes or exiting the exhaust vent.

Six-percent sodium hypochlorite was again introduced into the root canal system with the same irrigation technique as previously described with a standard, 12-ml Monoject syringe with ProRinse, 30-gauge, side-vented, closed-end needle. As determined by pilot study, 3 ml of 6.0-percent sodium hypochlorite was delivered (FIGURE 33 and TABLE I). The water delivery switch attached to the rheostat of the dental unit was turned "on." With a pool of sodium hypochlorite remaining within the access opening, the insert tube attached to the suction head of the Canal CleanMax handpiece was inserted into the canal to a point of apical binding or working length, choosing the shorter of the two. The foot pedal of the rheostat was depressed (FIGURE 65). The insert tube was progressed and retracted in pumping motion from level of canal orifice to previously determined apical stop for thirty seconds. Time was calculated by placement of the same analog clock in front of the operator and starting and stopping irrigation according to the second-hand (FIGURE 65). The water delivery switch attached to the rheostat of the dental unit was then turned "off." The insert tube was again progressed and retracted in pumping motion from level of canal orifice to previously determined apical stop until no moving solution was visible within the insert tubes or exiting the exhaust vent. No paper points were used in drying the root canal system.

Total volume of 6.0-percent sodium hypochlorite and 17-percent EDTA delivered during entire irrigation regimen was recorded (TABLE II). However, the Canal CleanMax also delivered sterile water from the dental unit for 30-second intervals during irrigation. Thus, the average amount of sterile water delivered from the Canal CleanMax over 30 seconds was determined (TABLE III). The water delivery switch attached to the rheostat of the dental unit was turned "on." The tip of the insert tube attached to the suction head of the Canal CleanMax handpiece was inserted just inside the rim of a 500 ml beaker (FIGURE 66). The foot pedal of the rheostat was depressed for 30 seconds. Time was calculated by placement of the same analog clock used during experimentation in front of the operator and starting and stopping irrigation according to the second-hand (FIGURE 66). Sterile water from the beaker was transferred to graduated cylinders for quantification (FIGURE 66). This process was performed a total of twelve times recording the volumes of sterile water delivered during each trial. Six trials were performed with the water reservoir tank of the dental unit less than or equal to 25-percent capacity. Six more trials were performed with the reservoir tank of the dental unit greater than or equal to 75-percent capacity. The highest and lowest recorded volumes were omitted prior to acquiring the mean volume of sterile water delivered by the Canal CleanMax over 30 seconds (TABLE III). This mean volume was then used to approximate the total volume of sterile water delivered by the Canal CleanMax during experimentation (FIGURE 39 and TABLE II).

UNMOUNTING

The plastic test tubes were scored with plumbing pipe cutting device, and separated from underlying VPS impression material (FIGURE 67). The teeth were

manually removed from VPS impression material (FIGURE 68). The adhesive was not attempted to be removed from root structure, but sticky wax and areas of gross debris and/or VPS were attempted to be removed with hand instruments.

CANAL SECTIONING AND COATING

A diamond coated separating disc loaded in a Dremel (Robert Bosch Tool Corporation, Racine, WI) rotary tool was utilized to incorporate a groove along the long axis of all teeth both on mesial and distal aspects of tooth structure to a depth approximating dentino-enamel junction using care not to penetrate the canal system with the disc (FIGURE 69). All teeth were then sectioned with a new surgical chisel and mallet along the previously incorporated mesial or distal groove (FIGURE 70). Sections were then evaluated selecting one longitudinal half for each section in which canal wall was most intact and consistent throughout the section. Selected sections were dried for two weeks in a vacuum desiccator loaded with silica gel granules (FIGURE 72). Samples were then sputter-coated with gold-palladium (Fine Coat Ion Sputter Denton Desk 2 model; LabX, Ontario Canada) prior to SEM analysis (FIGURE 73).

MICROSCOPIC EVALUATION

Coronal, middle, and apical thirds of root canal walls were examined using the JSM-5310 High Vacuum Scanning Electron Microscope by an independent dental SEM research technician/analyst (FIGURE 74). Photographs were taken at a magnification of X1000, and labeled.[330] An automated research randomizer was used to randomly number sixty photographs from each section of the root canal. These three groups of randomized photographs were then randomly labeled either “A,” “B,” or “C,” by the same research

randomizer.[331] Two independent examiners blindly analyzed and scored the randomized photographs to quantify the amount of residual debris and/or smear layer present along root canal walls. Each examiner scored all photographs twice allowing for at least two days between evaluations (APPENDIX II, APPENDIX III, APPENDIX IV, APPENDIX V, APPENDIX VI). Debris was defined as material that remained loosely adherent to root canal walls.[30] Smear layer was defined as a surface film of debris retained on dentin.[7] The amount of debris and/or smear layer present was scored by a hybrid of two previously proposed systems by Hulsmann et al.[6] and Al-Hadlaq et al,[322] as illustrated in a similar research project by Van.[332] Representative SEM photographs for each scoring category were acquired from similar concurrent studies.[333, 334] These representative photographs had received unanimously agreed upon scores from blinded examiners, and were used in our study to accompany the outlined scoring system (FIGURE 75).

Debris and Smear Layer Detection: X1000 Magnification

Score 1) A clean root canal with only few small debris/smear particles present or a majority of dentinal tubules open.

Score 2) A few small isles of debris/smear covering less than 25 percent of the root canal wall and/or some dentinal tubules open.

Score 3) Presence of many accumulations of debris/smear covering more than 25 percent but less than 50 percent of the root canal wall and/or only few dentinal tubules open.

Score 4) More than 50 percent of the root canal wall covered by debris/smear layer and/or no dentinal tubules opens.

STATISTICAL METHODS

Intra-examiner repeatability and inter-examiner agreement of the debris removal scores were assessed using two-way contingency tables, percent agreement, and weighted kappa statistics (TABLE IV and TABLE V). If the two examiners disagreed, they reached a 'forced consensus' after discussing the photograph (APPENDIX I, APPENDIX II, APPENDIX III, APPENDIX IV, APPENDIX V, APPENDIX VI). Using the consensus scores combined and separately for each of the three locations, the three methods were compared for differences in debris/smear layer removal scores using a Kruskal-Wallis test, which determined if there were any differences among the three groups. If the overall test was significant, Wilcoxon Rank Sum tests were used to compare each pair of groups (FIGURE 76 and TABLE VI). Using the consensus scores combined and separately for each of the three irrigation methods, the three locations were compared for differences in debris removal scores using a Kruskal-Wallis test, which determined if there were any differences among the three groups. If the overall test was significant, Wilcoxon Rank Sum tests were used to compare each pair of groups (FIGURE 77 and TABLE VII).

SAMPLE SIZE JUSTIFICATION

In a previous study by Van,[332] the within-group standard deviation for the debris removal scores was approximately 0.8. With a sample size of 20 teeth per group, the study will have 80-percent power to detect a difference of 0.7 between any two groups, assuming two-sided tests with a nonparametric adjustment at a 5.0-percent significance level. Sample size calculations were performed using PASS (NCSS, Kaysville, UT).

RESULTS

Total approximated delivered volumes of 6.0-percent sodium hypochlorite (all groups), 17-percent EDTA (all groups), and sterile water (Canal CleanMax) were calculated and recorded (FIGURE 39 and TABLE II). The control and Canal CleanMax groups each delivered a total of approximately 17 ml of 6.0-percent sodium hypochlorite over approximately 180 seconds and approximately 2 ml of 17-percent EDTA over approximately 30 seconds during the irrigation of each root canal. This provided a total volume of approximately 19 ml combined of 6.0-percent sodium hypochlorite and 17-percent EDTA delivered over approximately 210 seconds (FIGURE 39 and TABLE II). Both groups utilized standard, 12-ml, Monoject syringes equipped with 30-gauge ProRinse, side-vented, closed-end needles to deliver both irrigation solutions (FIGURE 8 and FIGURE 35). However, the suction head of the Canal CleanMax also delivered sterile water acquired from the dental unit during irrigation (FIGURE 65). The Canal CleanMax delivered a calculated mean of approximately 34 ml of sterile water over approximately 30 seconds (TABLE III). Approximately 102 ml of sterile water was delivered by the Canal CleanMax over approximately 90 seconds that it was used during experimentation. This provided a total volume of approximately 121 ml of a combination of 6.0-percent sodium hypochlorite, 17-percent EDTA, and sterile water over a total approximate irrigation time of 300 seconds (FIGURE 39 and TABLE II).

The EndoVac delivered a total of approximately 73 ml of 6.0-percent sodium hypochlorite over approximately 180 seconds and approximately 10 ml of 17-percent

EDTA over approximately 30 seconds during the irrigation of each root canal. This provided a total volume of approximately 83 ml combined of 6.0-percent sodium hypochlorite and 17-percent EDTA delivered over approximately 240 seconds. Thirty seconds was added to the total irrigation time with 6.0-percent sodium hypochlorite as compared to the control and Canal CleanMax groups due to additional irrigation with the MicroCannula. Sterile water was not utilized in the irrigation of any root canals in the EndoVac group (FIGURE 39 and TABLE II).

The intra-examiner repeatability analysis for examiner one (JB) was acceptable with good agreement (weighted kappa=0.75). Disagreements usually were due to a lower score on the repeat evaluation (TABLE IV). Intra-examiner repeatability analysis for examiner two (SB) was also acceptable with good agreement (weighted kappa=0.74). Disagreements were usually due to a higher score on the repeat evaluation (TABLE IV). The inter-examiner agreement analysis showed good agreement between both examiners (weighted kappa = 0.62) Disagreements were usually caused by lower scores given by examiner one (JB) than by examiner two (SB). As anticipated, the weighted kappa was slightly lower for inter-examiner analysis than that of the intra-examiner analysis (TABLE V).

The two examiners' original and consensus canal debris/smear layer scores for randomized, anonymously labeled SEM photographs from the coronal (B), middle (A), and apical (C) sections, in which the examiners were blinded, are illustrated in the appendices (APPENDIX I, APPENDIX II, APPENDIX III). The final consensus debris/smear layer scores for these randomized, anonymously labeled SEM photographs

matched with the actual study group and location in which they represented are also illustrated in the appendices (APPENDIX IV, APPENDIX V, and APPENDIX VI).

All of the original 60 teeth chosen for experimentation met inclusion criteria for further SEM analysis. No teeth were replaced or removed from the study. When debris/smear layer scores between groups was compared for each location along the root canal walls, the coronal third exhibited significant differences in debris scores among groups ($p = 0.0327$), with significantly lower scores for EndoVac than control ($p = 0.0119$) and no significant difference between Canal CleanMax and control (0.3965) or Canal CleanMax and EndoVac ($p = 0.1196$). The middle third of root canals walls did not exhibit significant differences in debris scores among groups ($p = 0.3877$) and none of the pairwise differences were significant. The apical third of root canal walls did not exhibit significant differences in debris scores among groups ($p = 0.8619$) and none of the pairwise differences were significant. When all locations of root canal walls were combined a marginally significant difference was noted in debris scores among groups ($p=0.0873$), with significantly lower scores for EndoVac than control ($p = 0.0326$) and no significant difference between Canal CleanMax and control (0.4019) or Canal CleanMax and EndoVac ($p = 0.1663$). All comparisons in mean debris/smear layer scores at coronal (B), middle (A), apical (C), and combined sections of all specimens for Group one (control), Group two (EndoVac), and Group three (Canal CleanMax) are illustrated in FIGURE 76 and TABLE VI.

When debris/smear layer scores in locations were compared, the control group exhibited marginally significant differences in debris scores among groups ($p = 0.0703$), with significantly lower scores for middle than apical thirds ($p = 0.0298$) and no

significant difference between coronal and middle thirds (0.2120), or coronal and apical thirds (p=0.2917). The EndoVac group exhibited significant differences in debris scores among groups (p = 0.0004), with significantly lower scores for both coronal and middle thirds than apical thirds (p = 0.0015 and 0.0021), and no significant difference between coronal and middle (0.9627) thirds. The Canal CleanMax group exhibited marginally significant differences in debris scores among groups (p = 0.0794), with significantly lower scores for middle than apical thirds (p = 0.0329), and no significant difference between coronal and middle thirds (0.5889), or coronal and apical (p = 0.1459) thirds. When all locations were combined, there were significant differences in debris scores noted among groups (p = <0.0001), with significantly lower scores for both coronal and middle thirds than apical thirds (p = 0.0006 and p < 0.0001) and no significant difference between coronal and middle thirds (0.2812). All comparisons of mean debris/smear layer scores between group one (Control), Group two (EndoVac), group 3 (Canal CleanMax), and combined groups at each location of all specimens are illustrated in FIGURE 77 and TABLE VII.

The mean debris/smear layer scores for group one (control) ranged from 2.1 (middle) to 2.9 (apical), which equates to less than 25 percent of examined root canal wall occupied by debris and/or smear layer after hand-rotary instrumentation and irrigation with a standard 12-ml Monoject syringe with a ProRinse, 30-gauge, side-vented, closed-end needle. The coronal third of root canals surprisingly exhibited a debris/smear layer score (2.5) higher than that of the middle third (2.1) of root canals. However, these differences were not statistically significant. The control group exhibited the highest debris/smear layer scores in each third of the root canal separately and in all

areas combined of the root canal system. These differences were not statistically significant (FIGURE 77 and TABLE VII).

The mean debris/smear layer scores for group two (EndoVac) ranged from 1.6 (coronal and middle) to 2.9 (apical), which again equates to less than 25 percent of examined root canal wall occupied by debris and/or smear layer after hand-rotary instrumentation and irrigation. The EndoVac provided the lowest debris/smear layer scores of all groups both in the coronal and middle thirds of root canal walls examined. However, these values were not statistically significant (FIGURE 77 and TABLE VII).

The mean debris/smear layer scores for group three (Canal CleanMax) ranged from 2.0 (middle) to 2.8 (apical), which again equates to less than 25 percent of examined root canal wall occupied by debris and/or smear layer after hand-rotary instrumentation and irrigation. Like the control group, the coronal third of root canals surprisingly exhibited a debris/smear layer score (2.2) higher than that of the middle third (2.0) of root canals. However, these differences were not statistically significant. The Canal CleanMax produced the lowest debris/smear layer scores in the apical third of root canals when compared to the control and EndoVac groups. Unfortunately, these differences were not statistically significant (FIGURE 77 and TABLE VII).

The apical third of root canals exhibited the highest debris/smear layer score (2.9) when all groups were combined and compared to the combined group scores of the coronal (2.1) and middle thirds (1.9). Unfortunately, there were no significant differences in debris/smear layer scores between groups in the apical third of root canals. In fact, the debris/smear layer scores for the control group (2.9), EndoVac group (2.9), and Canal CleanMax group (2.8) exhibited the least amount of numerical difference

compared to other locations within the root canal system (FIGURE 76, FIGURE 77, TABLE VI, TABLE VII).

Even though the study was powered based on smaller standard deviations than were observed and is thus underpowered to detect differences, pairwise comparisons based on marginal overall significance should be viewed with caution since no adjustments were made for multiple comparisons.

FIGURES AND TABLE

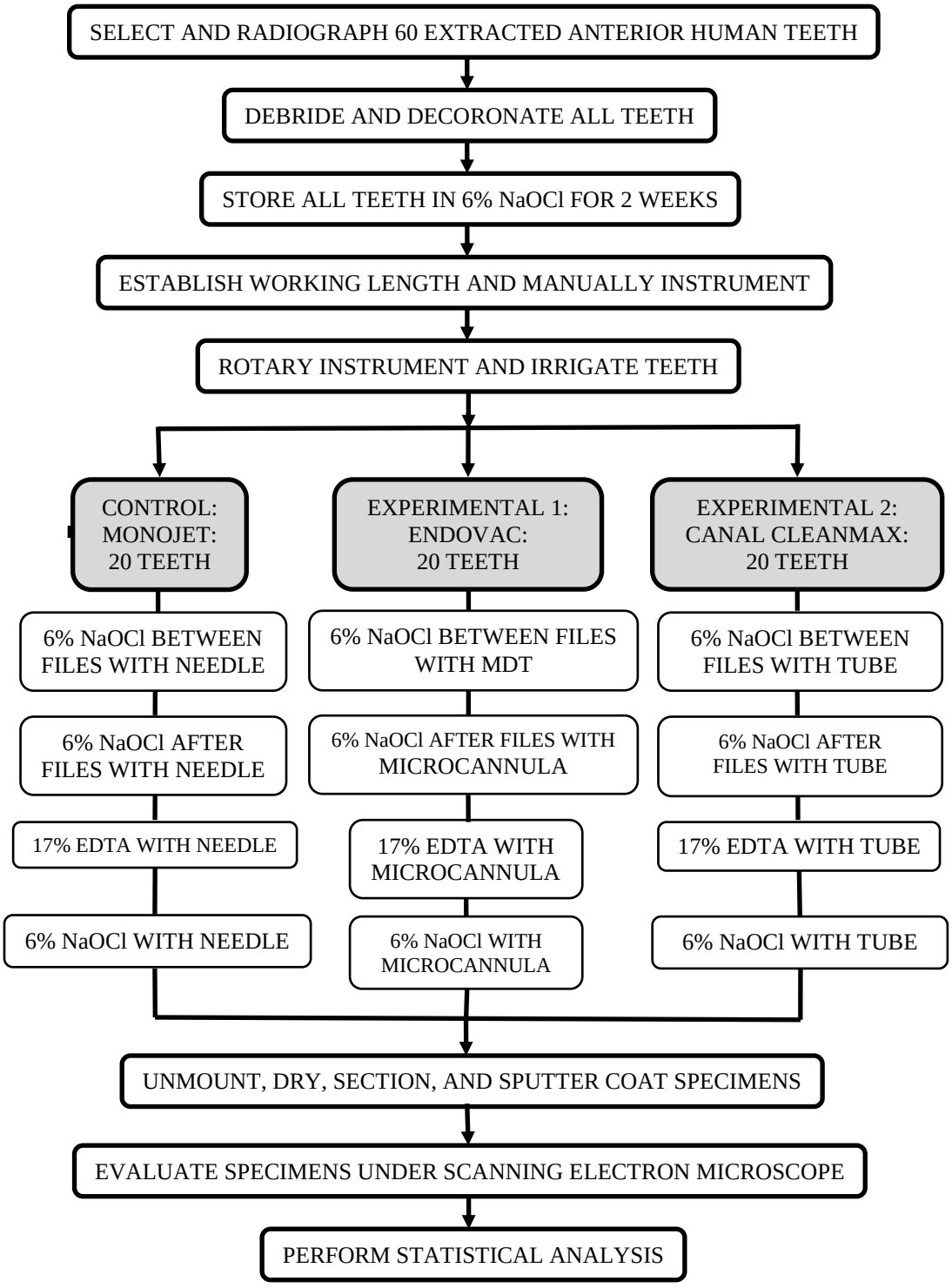

FIGURE 1. Summary of experimental design.

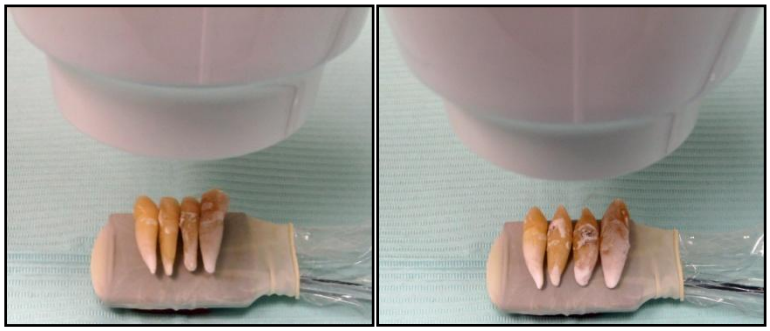

FIGURE 2. Pre-operative radiographs from facial-lingual and mesial-distal directions.

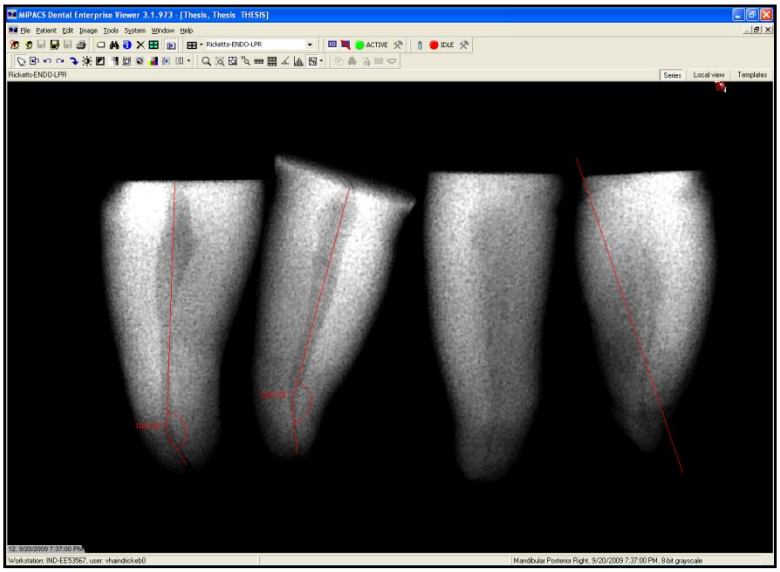

FIGURE 3. Canal curvature determination via MiPACS™ digital radiograph software.

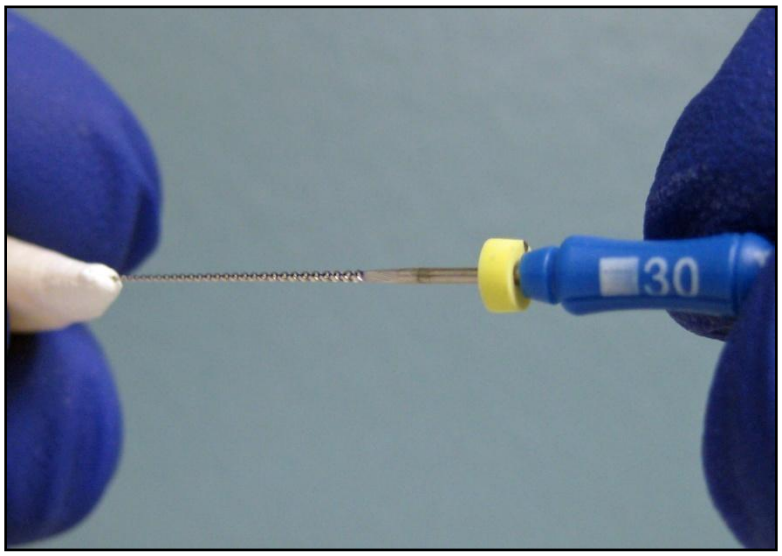

FIGURE 4. Pre-operative apical gauging with #30 K-type file.

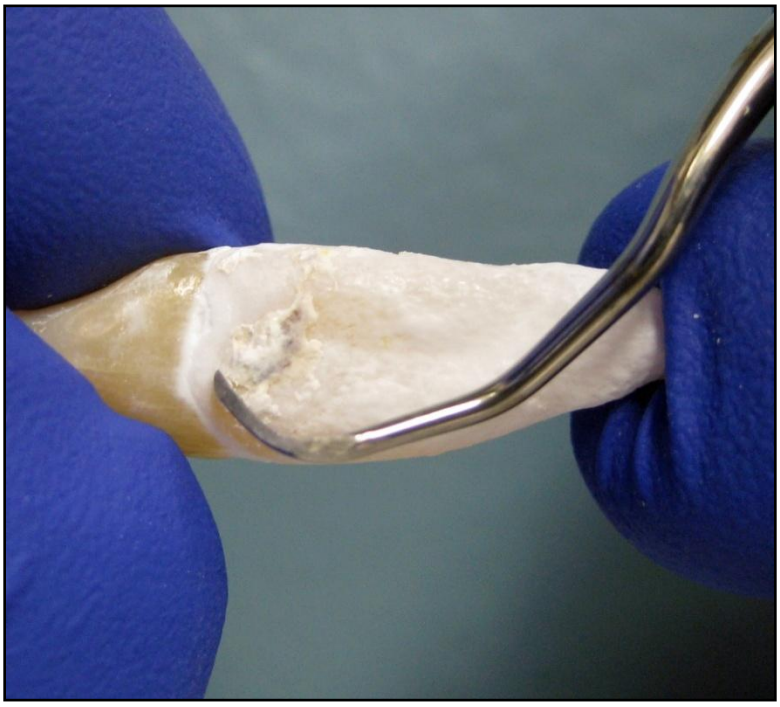

FIGURE 5. Scaling accretions from external root surface.

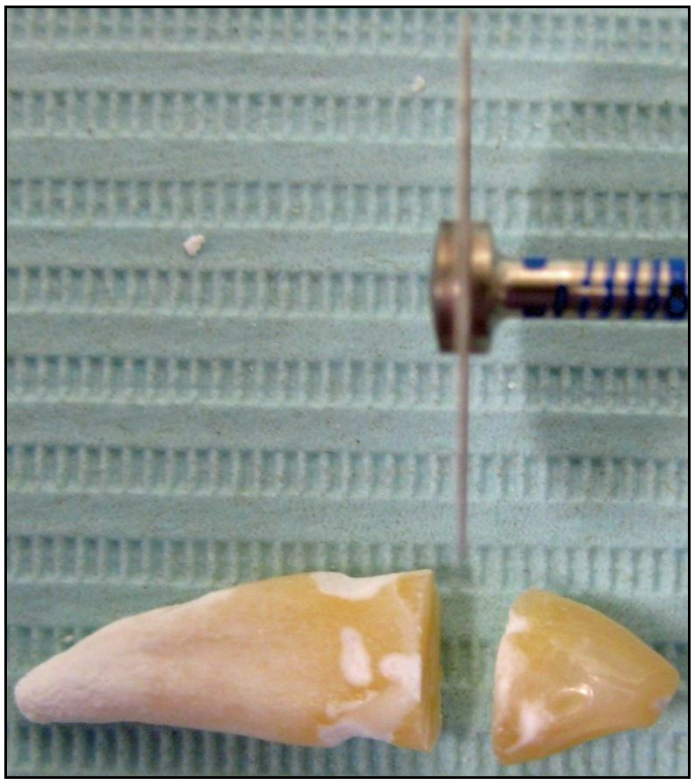

FIGURE 6. Decoronation with diamond-coated separating disc.

FIGURE 7. Initial setup prior to hand instrumentation.

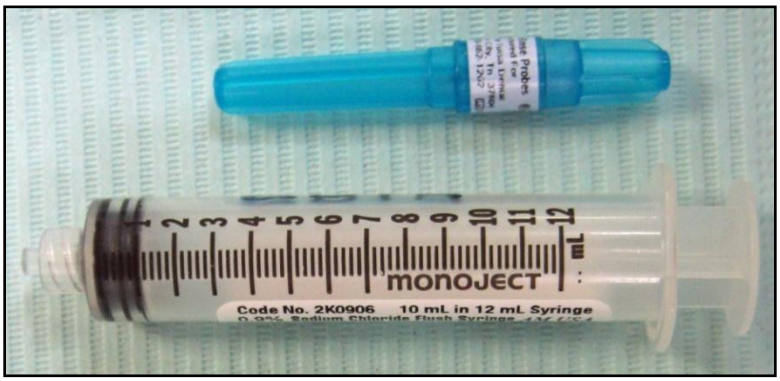

FIGURE 8. Twelve-ml Monoject syringe and ProRinse 30-gauge needle.

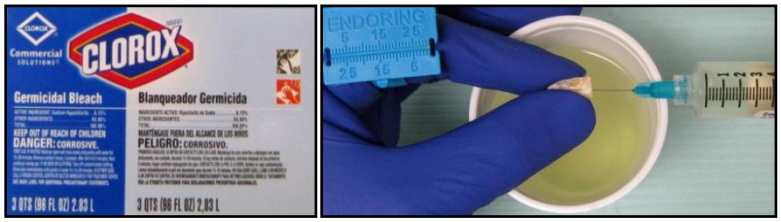

FIGURE 9. Introduction of 1 mm of sodium hypochlorite prior to instrumentation.

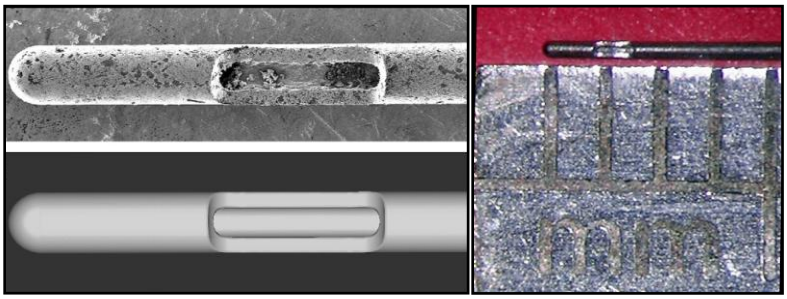

FIGURE 10. Scanning electron microscope (SEM) micrograph,[335] computer assisted design (CAD) image,[335] and surgical operating microscope photograph of side-vented, closed-end endodontic irrigation needle.

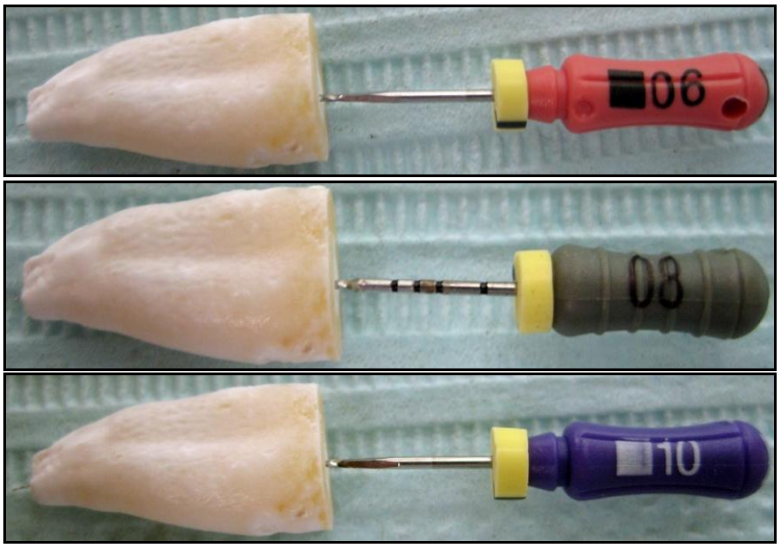

FIGURE 11. Establishment of apical patency.

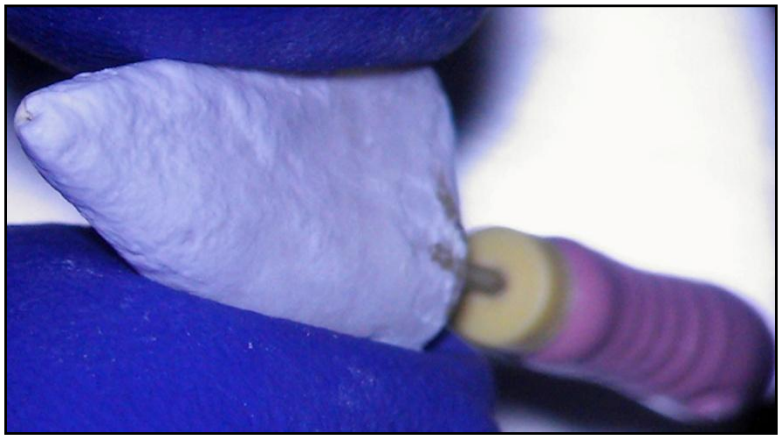

FIGURE 12. Root length determination via microscopic visualization.

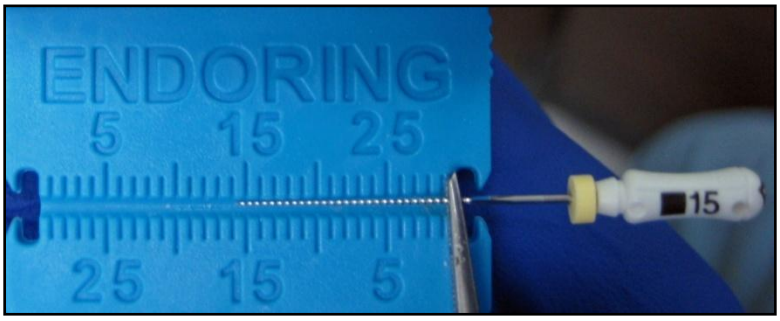

FIGURE 13. Subtraction of 1 mm from root length for working length.

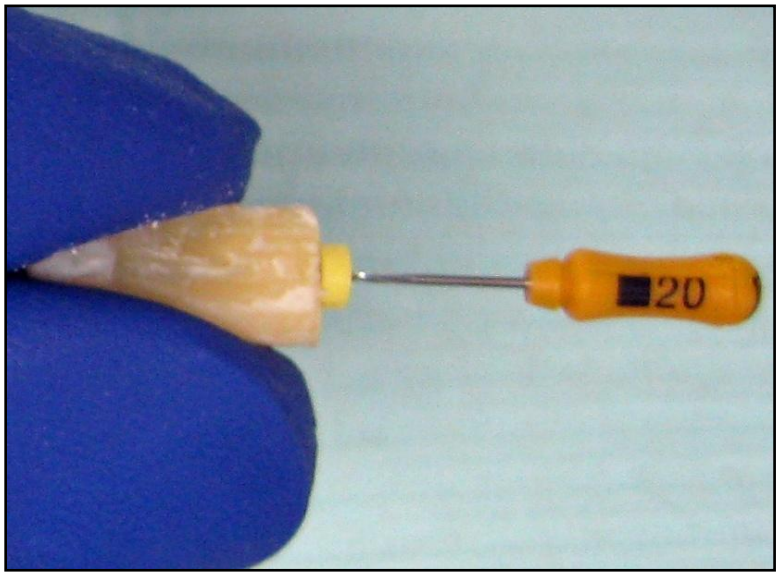

FIGURE 14. Final hand instrumentation to #20 K-type file.

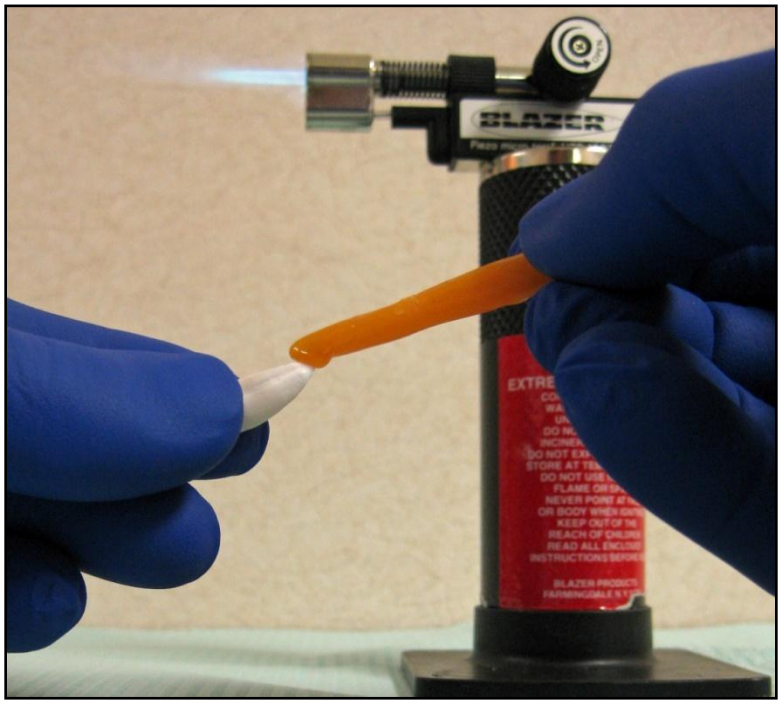

FIGURE 15. Heating and application of sticky-wax to root apices.

FIGURE 16. Application of vinyl-polysiloxane (VPS) adhesive to roots.

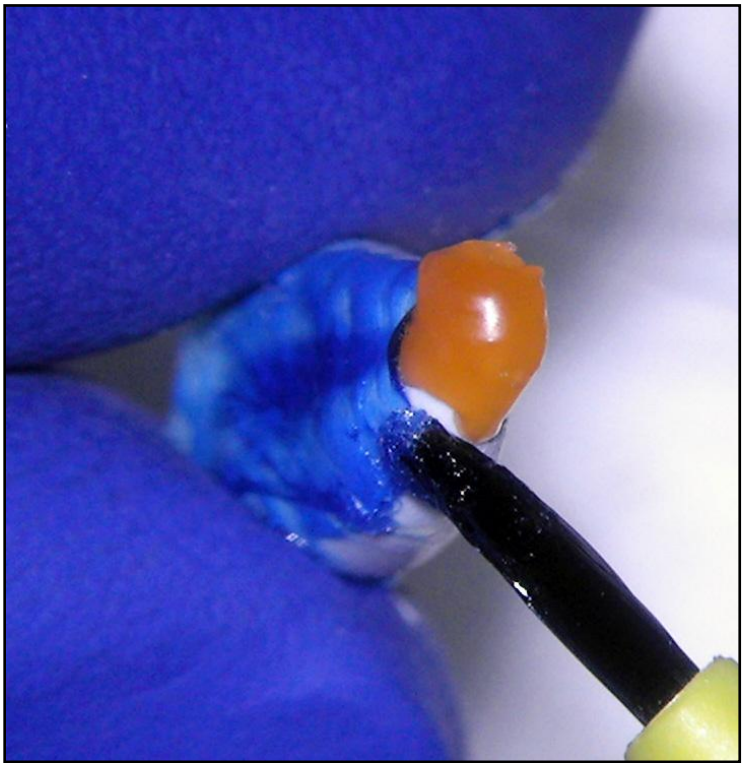

FIGURE 17. Microscopic evaluation of root apices after sticky-wax and vinyl-polysiloxane (VPS) adhesive applied.

FIGURE 18. Test tubes loaded with vinyl-polysiloxane (VPS) impression material.

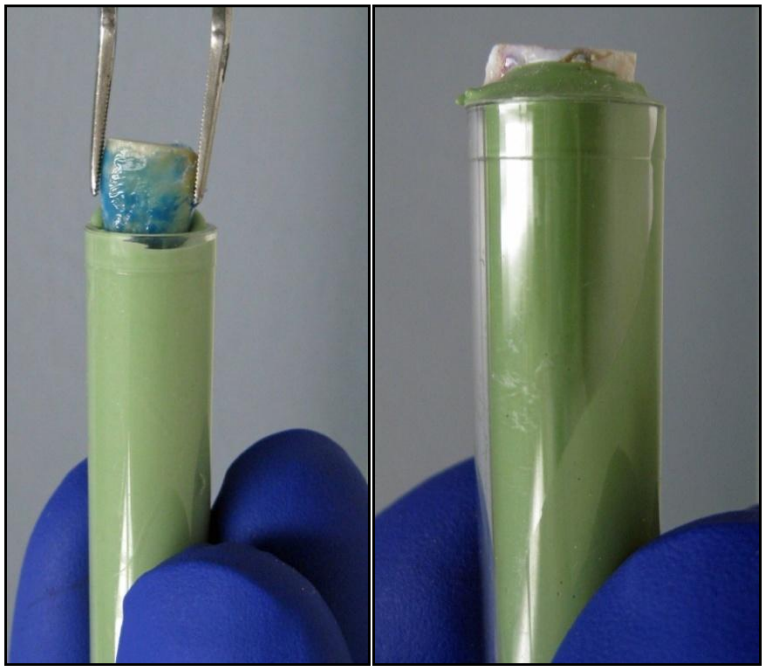

FIGURE 19. Roots submerged into test tubes filled with impression material.

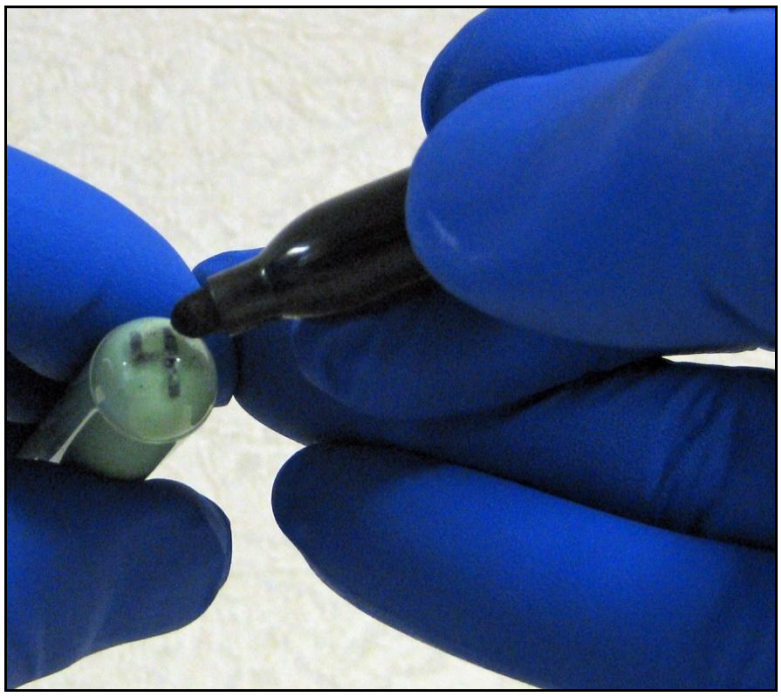

FIGURE 20. Labeling test tubes with working lengths of housed roots.

FIGURE 21. Sealed, test-tube storage of roots between laboratory sessions.

FIGURE 22. ProTaper nickel-titanium rotary file system.

FIGURE 23. Aseptico Endo ITR™ electric motor.

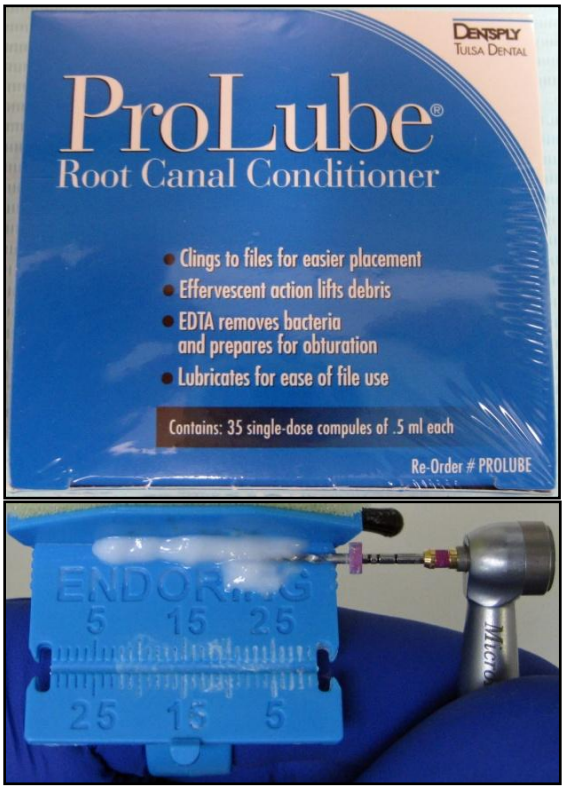

FIGURE 24. ProLube lubricant applied to ProTaper rotary files.

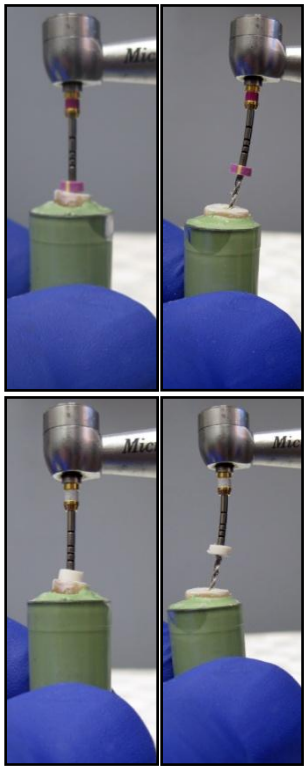

FIGURE 25. Instrumentation with ProTaper S1 and S2 rotary files using brushing motion.

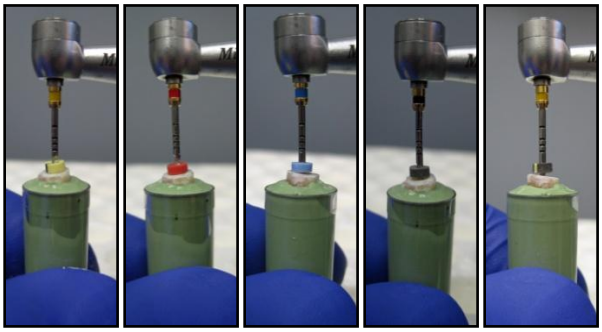

FIGURE 26. Instrumentation with ProTaper F1, F2, F3, F4, and F5 rotary files using in-out motion.

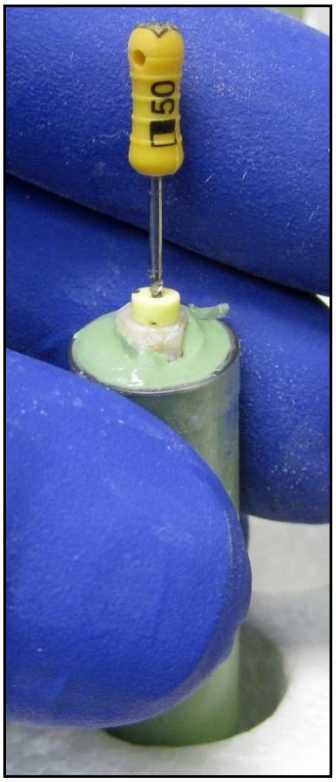

FIGURE 27. Confirmation of apical stop with #50 K-type file.

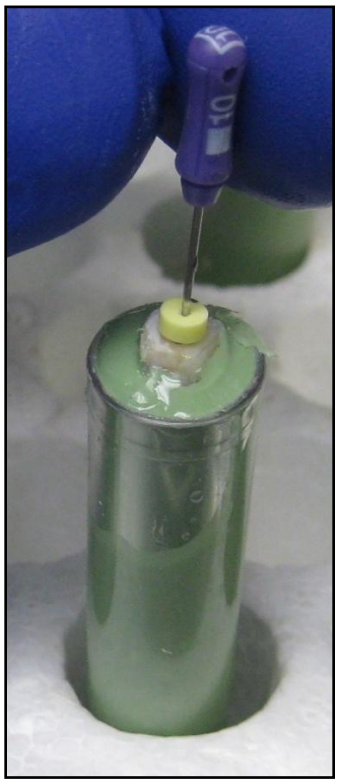

FIGURE 28. Recapitulation with #10 K-type file after rotary instrumentation.

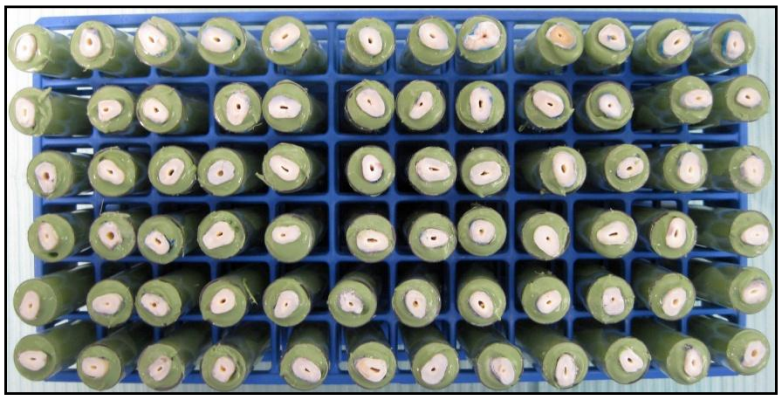

FIGURE 29. Examination of roots prior to randomization and grouping.

FIGURE 30. Exclusion of samples prior to randomization and grouping.

FIGURE 31. Mixing of samples for randomization.

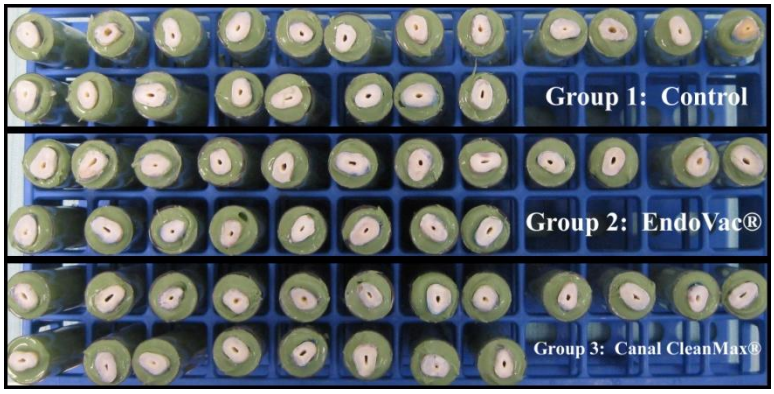

FIGURE 32. Grouping of samples.

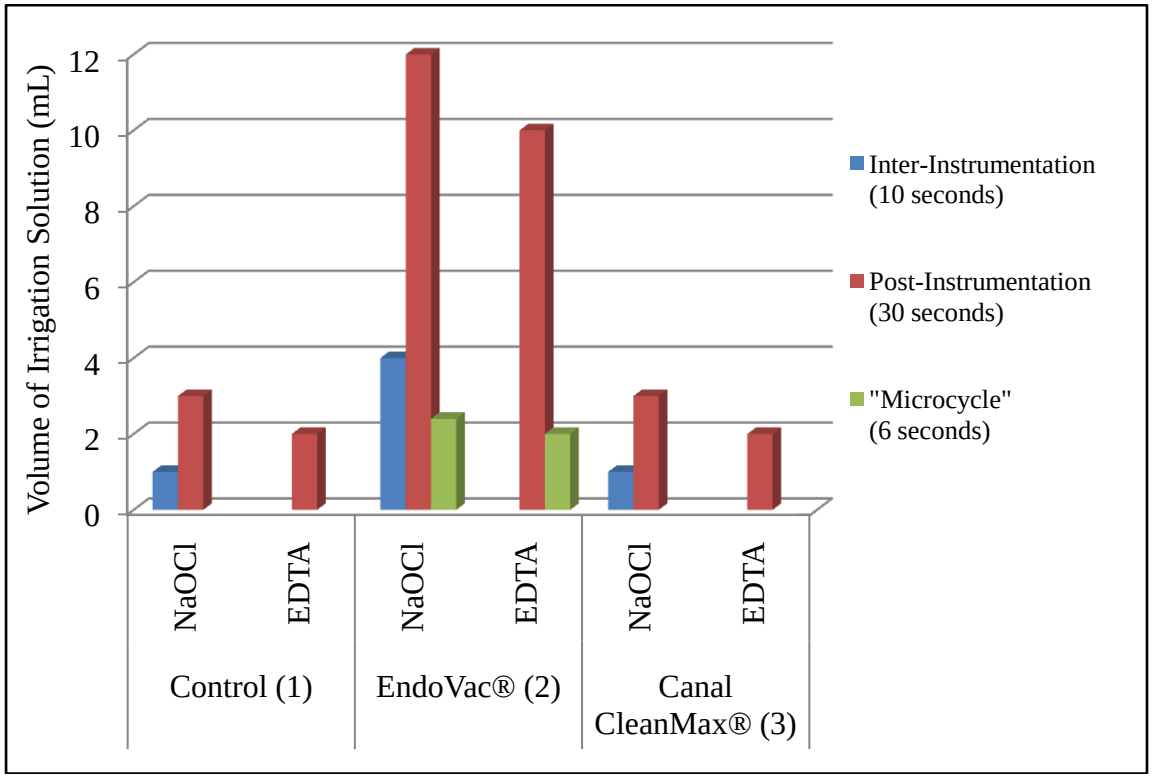

FIGURE 33. Pilot study, standardized volumes (ml) of irrigation solutions to be utilized.

FIGURE 34. Calculation of volumes of irrigation solution to be utilized with the Monoject syringe and ProRinse needle (Left) or Master Delivery Tip (Right).

FIGURE 35. Two, 12-ml Monoject syringes loaded with 17-percent EDTA and 6.0-percent sodium hypochlorite.

FIGURE 36. Delivery of 1 ml of 6.0-percent sodium hypochlorite via Monoject syringe equipped with a ProRinse, 30-gauge, side-vented, closed-end needle.

FIGURE 37. Delivery of 2 ml of 17-percent EDTA via Monoject syringe equipped with a ProRinse, 30-gauge, side-vented, closed-end needle.

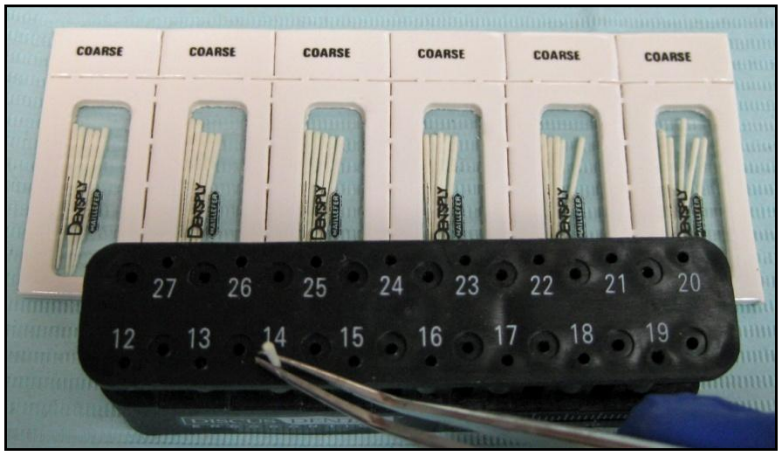

FIGURE 38. Measurement of paper points prior to drying of root canals.

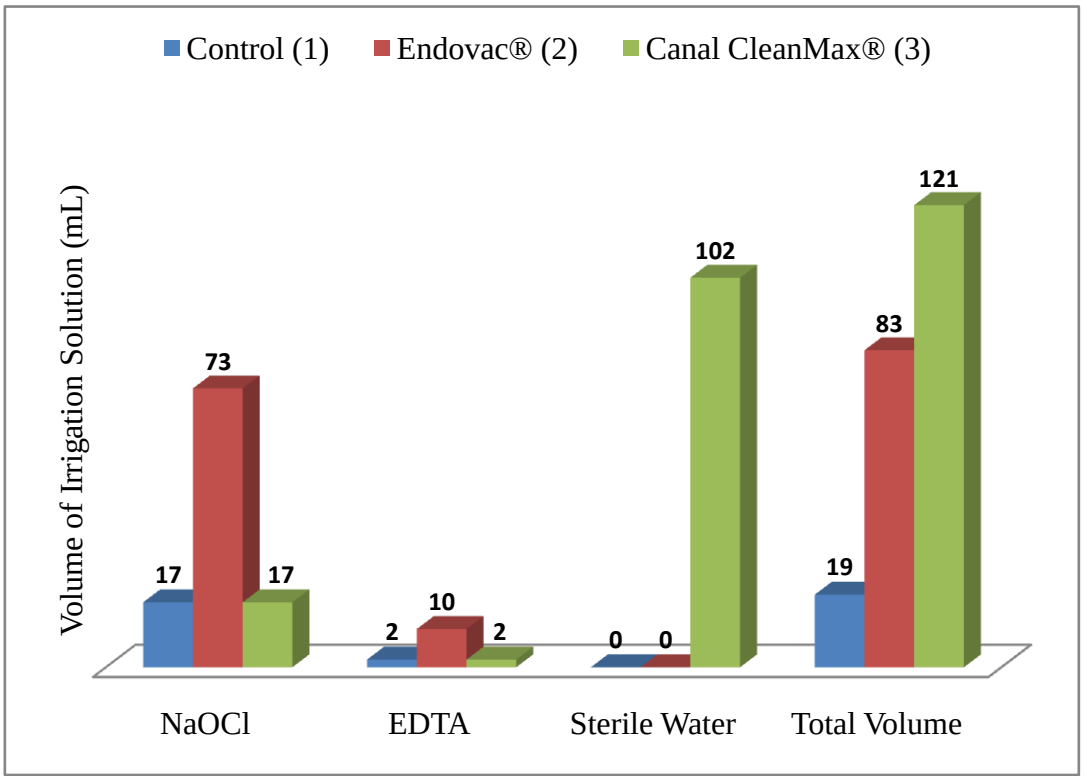

FIGURE 39. Total volume (mL) of irrigation solutions delivered during irrigation.

FIGURE 40. The EndoVac System.

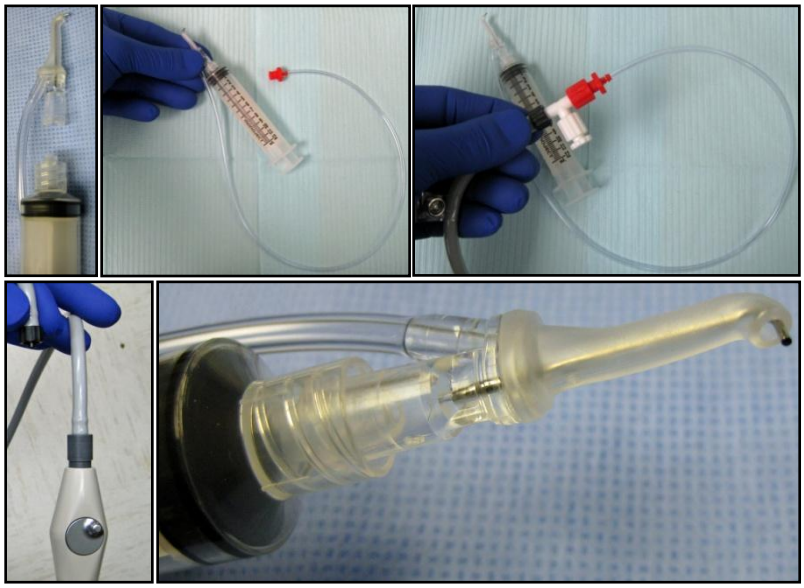

FIGURE 41. Master Delivery Tip (MDT) assembly and connection.

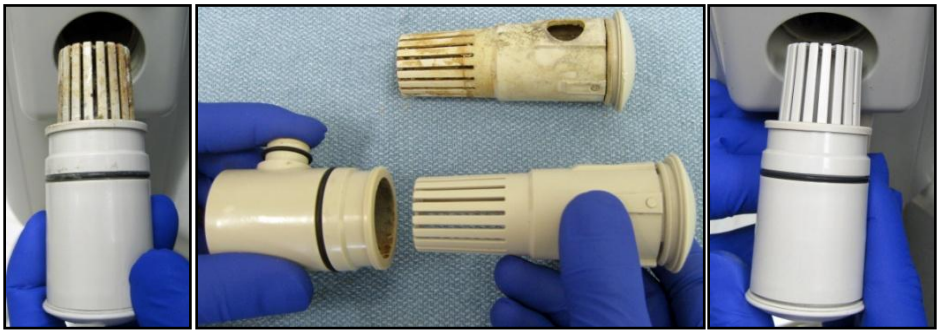

FIGURE 42. Replacing trap from dental unit's suction system prior to irrigation with the EndoVac.

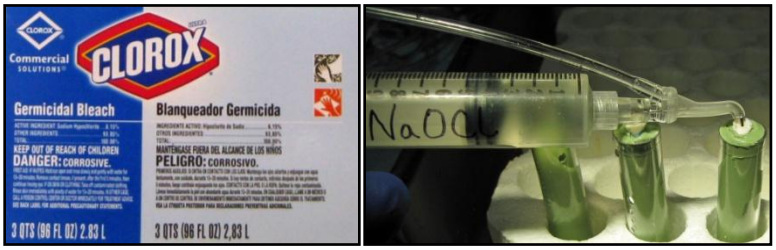

FIGURE 43. Delivery of 6.0-percent sodium hypochlorite with 12-ml Monoject syringe equipped with Master Delivery Tip (MDT).

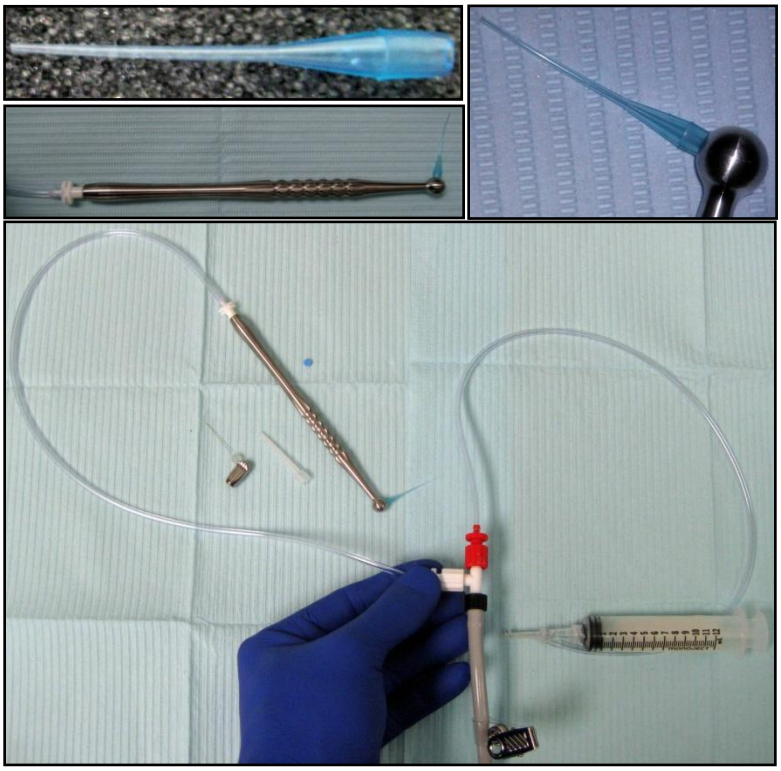

FIGURE 44. MacroCannula assembly and connection.

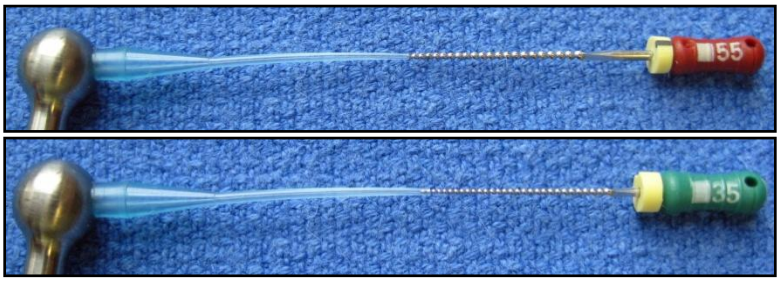

FIGURE 45. Illustration of MacroCannula outer lumen diameter of 0.55 mm and inner lumen diameter of 0.35 mm as compared with Lexicon K-type files of the same size.

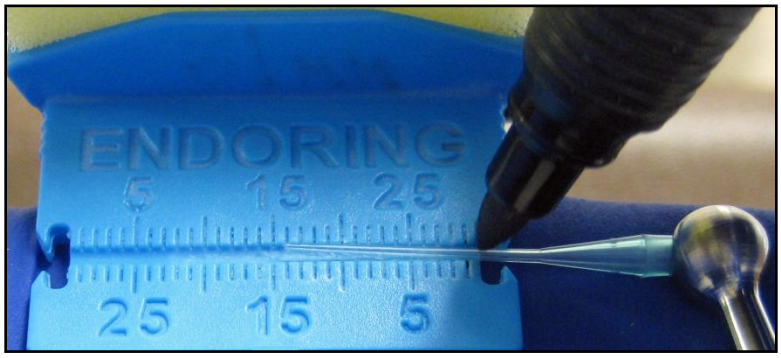

FIGURE 46. Marking MacroCannula at appropriate working length.

FIGURE 47. Delivery of 6.0-percent sodium hypochlorite with Master Delivery Tip (MDT) and MacroCannula.

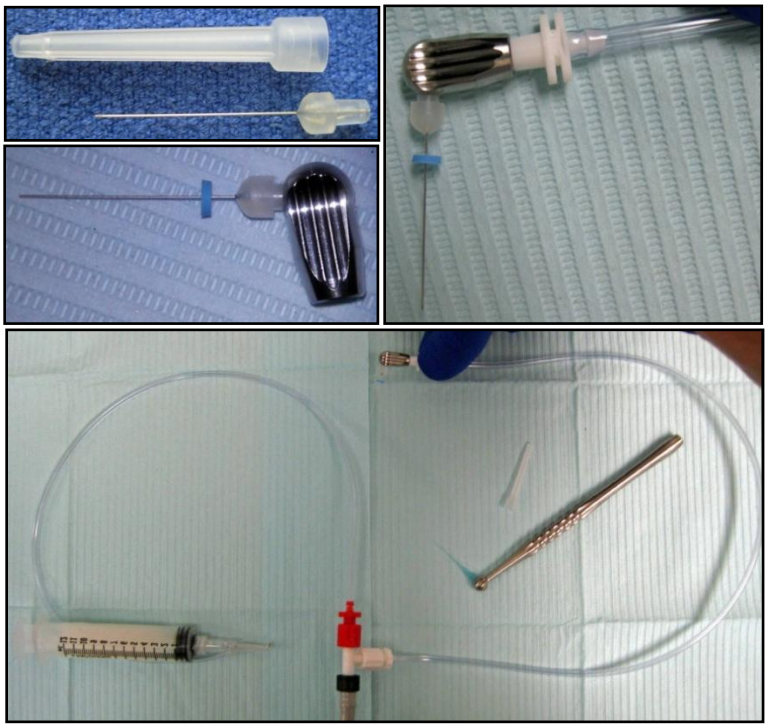

FIGURE 48. MicroCannula assembly and connection.

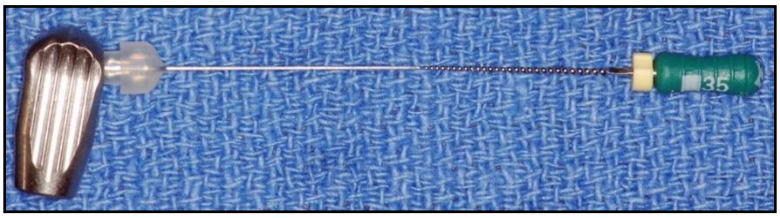

FIGURE 49. Illustration of 0.32-mm MicroCannula compared with Lexicon #35 K-type file.

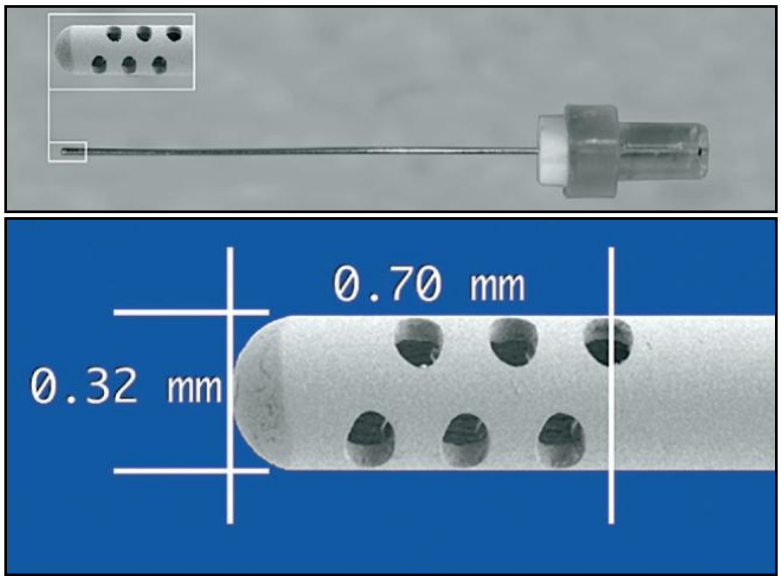

FIGURE 50. Magnified spherical, welded-end of MicroCannula illustrating micro-holes.[44]

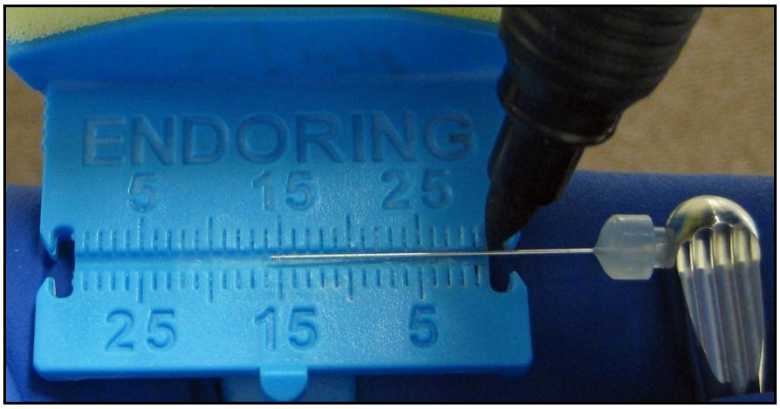

FIGURE 51. Marking MicroCannula at appropriate working length.

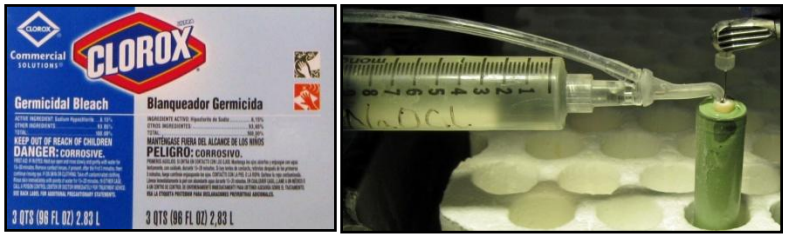

FIGURE 52. Delivery of 6.0-percent sodium hypochlorite with Master Delivery Tip (MDT) and MicroCannula.

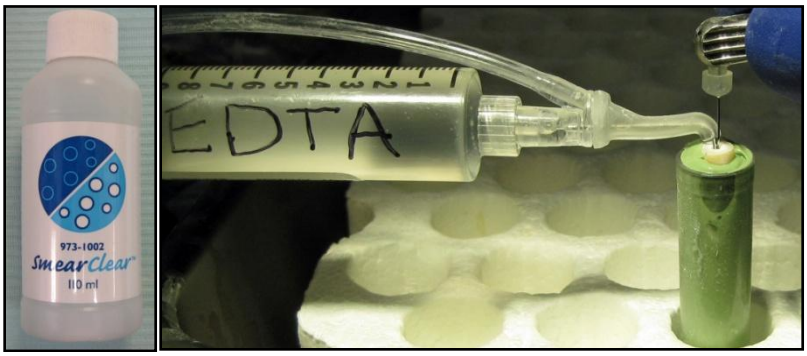

FIGURE 53. Delivery of 17-percent EDTA with Master Delivery Tip (MDT) and MicroCannula.

FIGURE 54. The Canal CleanMax System.

FIGURE 55. The Canal CleanMax assembly and connections.

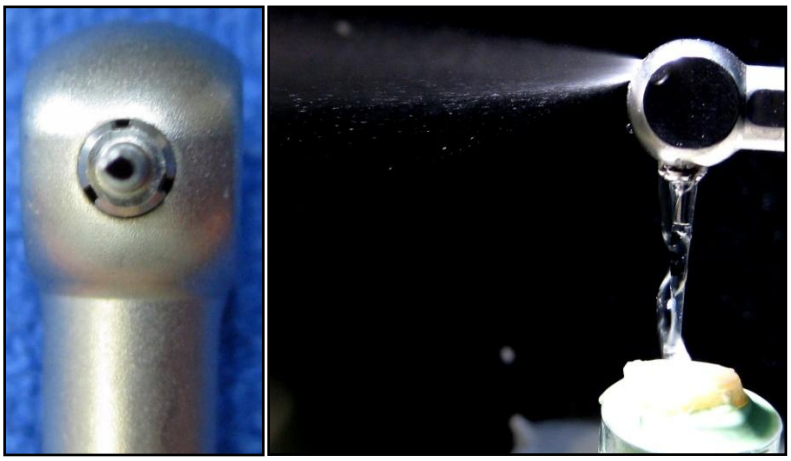

FIGURE 56. Water delivery holes from base of suction head of Canal CleanMax.

FIGURE 57. Power control ring of the Canal CleanMax.

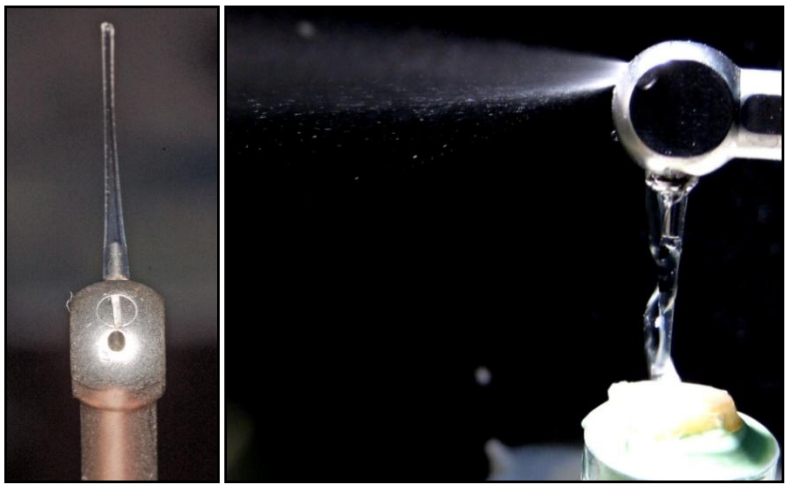

FIGURE 58. Exhaust vent of the Canal CleanMax.

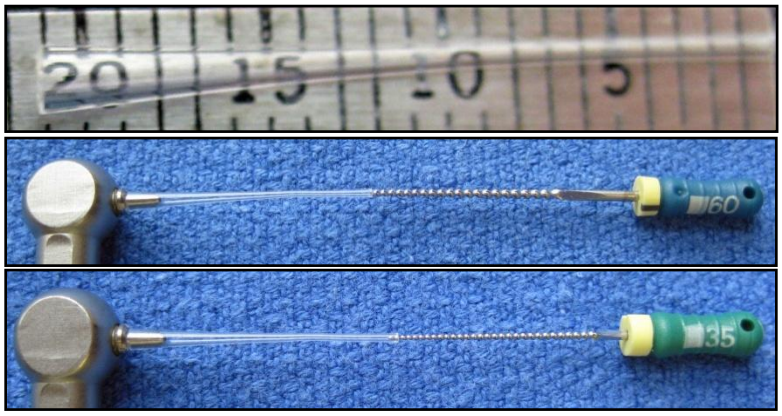

FIGURE 59. Illustration of length of insert tube and its outer lumen diameter of 0.60 mm and inner lumen diameter of 0.35 mm as compared with Lexicon K-type files of the same size.

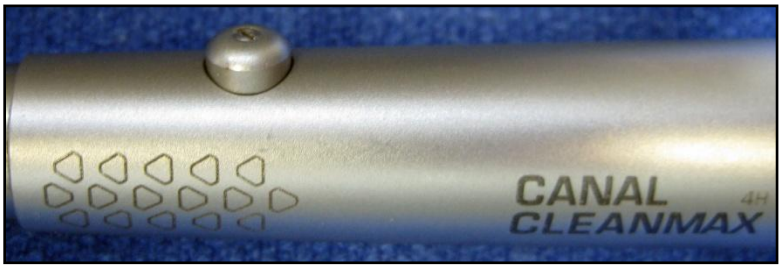

FIGURE 60. The one-push cleaning system of the Canal CleanMax.

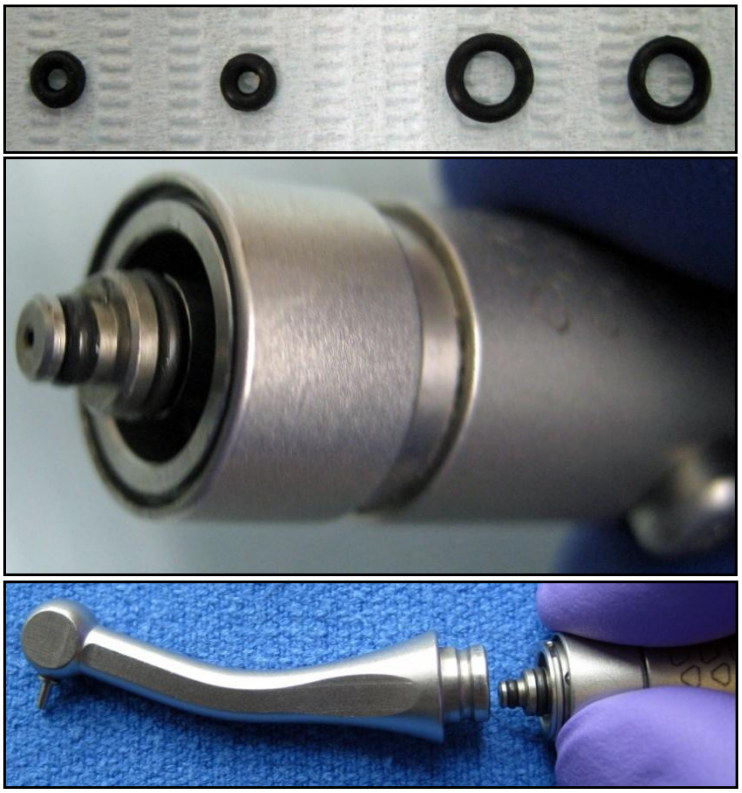

FIGURE 61. Replacement of O-rings of Canal CleanMax handpiece.

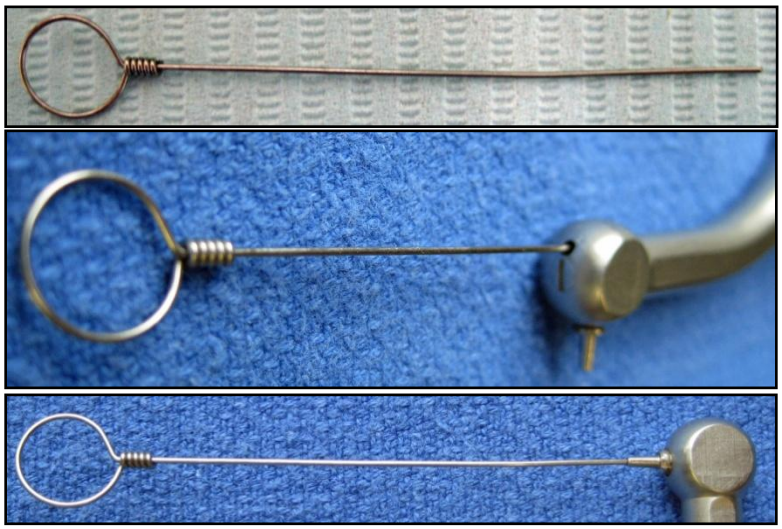

FIGURE 62. Cleaning of the suction head of Canal CleanMax with cleaning wire.

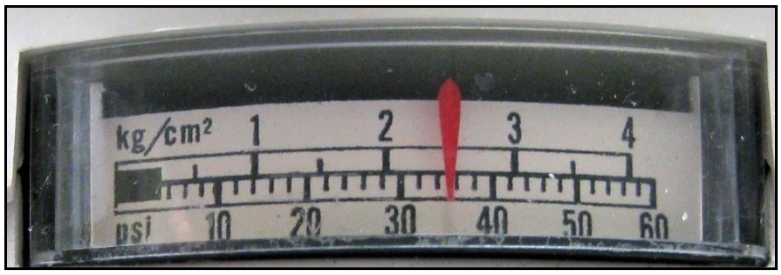

FIGURE 63. Adjusting dental unit to deliver 35 lbs per square inch of compressed air to high speed handpiece prior to connection of Canal CleanMax.

FIGURE 64. Marking insert tube of Canal CleanMax at appropriate working length.

FIGURE 65. Irrigation with the Canal CleanMax for 30 seconds delivering sterile water from the dental unit while 6.0-percent sodium hypochlorite remained in root canals.

FIGURE 66. Determination of volume of sterile saline delivered from Canal CleanMax over 30 seconds.

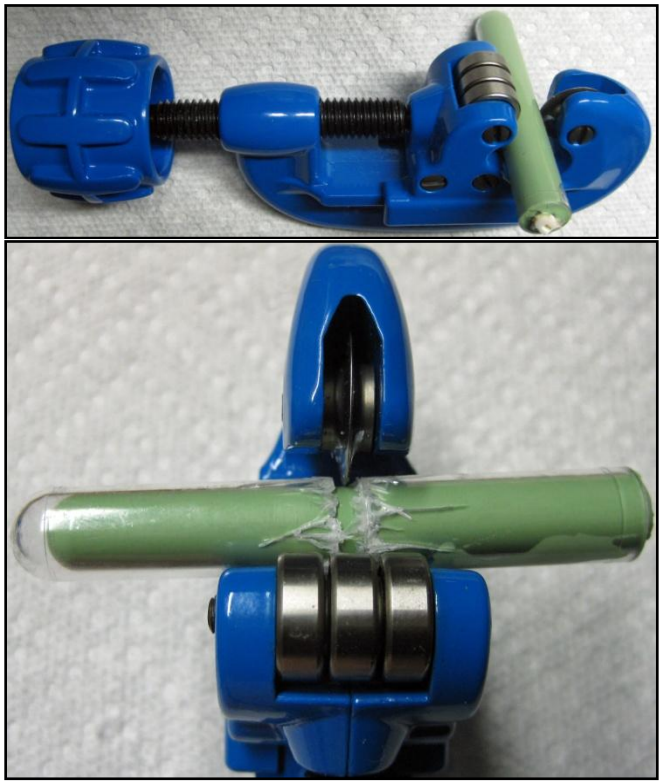

FIGURE 67. Plastic test tubes scored with plumbing pipe cutting device and separated from impression material.

FIGURE 68. Removing tooth from impression material.

FIGURE 69. Incorporation of mesial and distal longitudinal grooves in roots to approximate canal space.

FIGURE 70. Sectioning roots with a new surgical chisel and mallet along the previously incorporated mesial or distal groove.

FIGURE 71. Evaluation of longitudinal roots sections selecting the more consistent and intact root canal system.

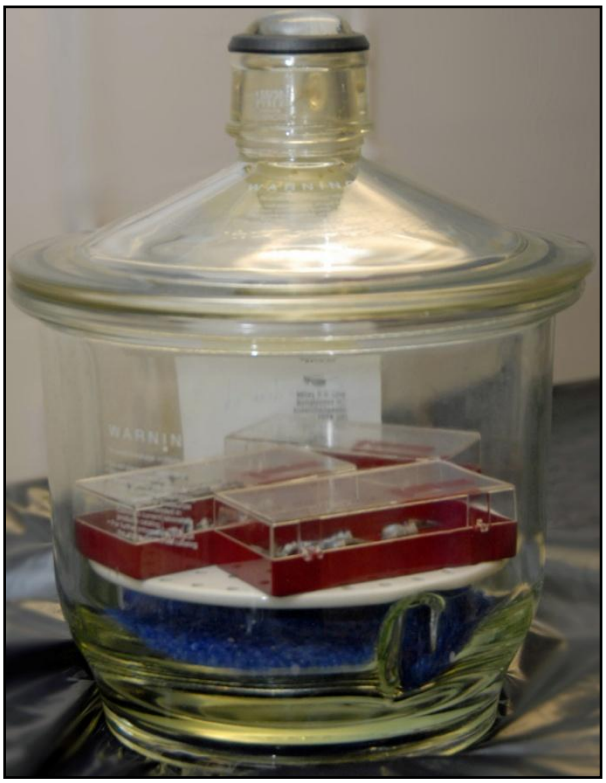

FIGURE 72. Teeth dried in dessicator for two weeks.[333, 334]

FIGURE 73. Specimens sputter-coated with gold-palladium.[333, 334]

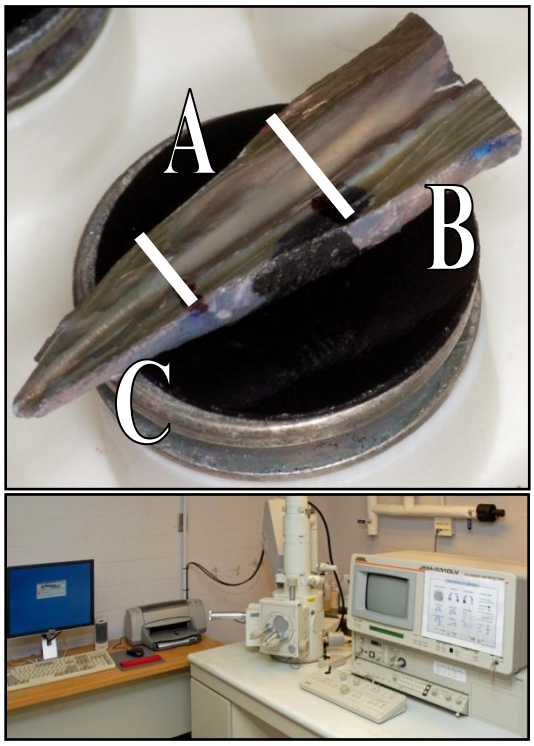

FIGURE 74. Evaluation of coronal (B), middle (A), and apical (C) thirds of root canals with JSM-5310 High Vacuum Scanning Electron Microscope.

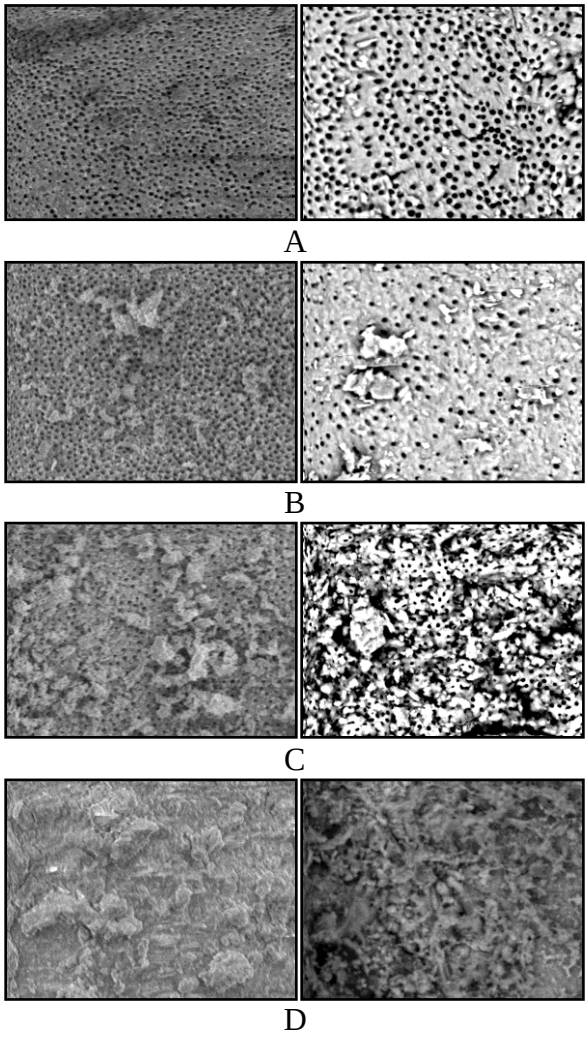

FIGURE 75. Representative SEM photographs for specimens with (A) smear/debris score 1, (B) smear /debris score 2, (C) smear/debris score 3 and (D) smear/debris score 4.[333, 334]

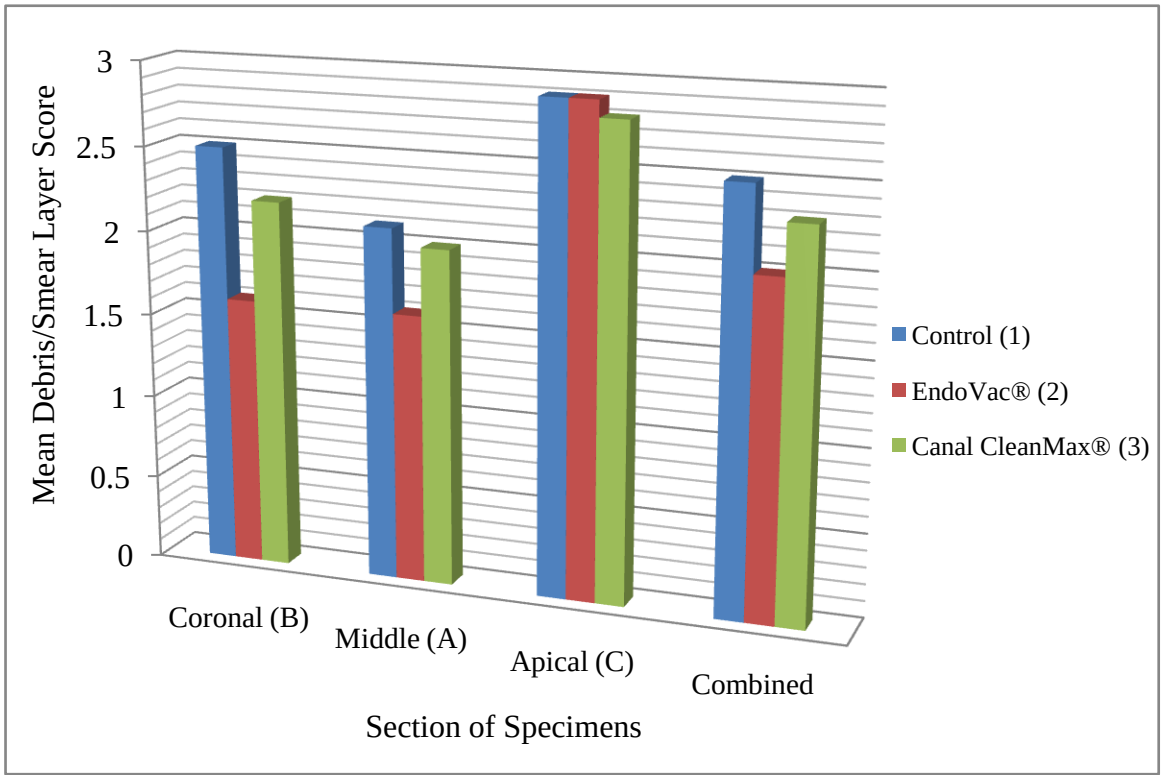

FIGURE 76. Comparison of mean debris/smear layer scores at coronal (B), middle (A), apical (C), and combined sections of all specimens for Group 1 (control), Group 2 (EndoVac), and Group 3 (Canal CleanMax).

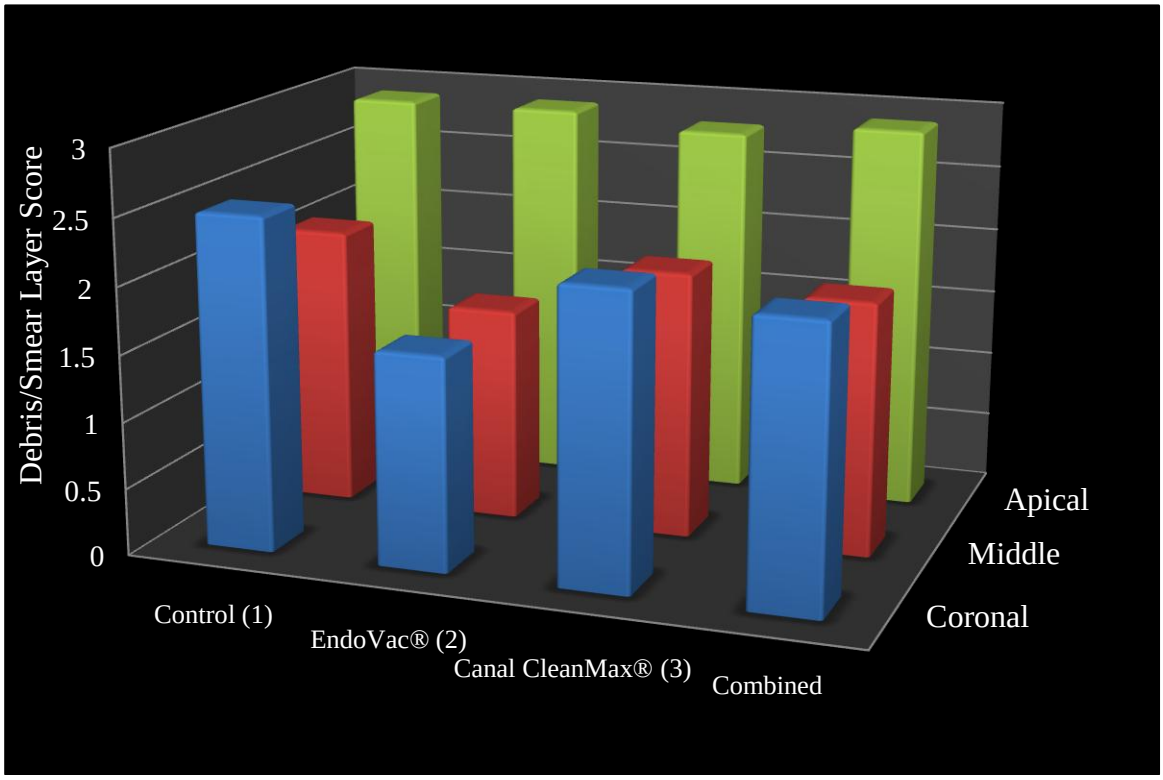

FIGURE 77. Comparison of mean debris/smear layer scores between Group (Control), Group 2 (EndoVac), Group 3 (Canal CleanMax), and combined groups at each location of all specimens.

FIGURE 78. Multiple reservoir irrigation unit for the Canal CleanMax.[51]

FIGURE 79. The multiport adapter of the EndoVac System.[49]

TABLE I

Standardized volumes (mL) of irrigation solutions to be utilized in pilot study

Group	Solution	Inter-Instrumentation (10 seconds)	Post-Instrumentation (30 seconds)	"Microcycle" (6 seconds)
Control (1)	NaOCl	1	3	
	EDTA		2	
EndoVac (2)	NaOCl	4	12	2.4
	EDTA		10	2
Canal CleanMax (3)	NaOCl	1	3	
	EDTA		2	

TABLE II

Total volume (mL) of irrigation solutions delivered
over time intervals (seconds) of irrigation

	NaOCl	Time	EDTA	Time	Sterile Water	Time	Total Volume	Total Time
Control (1)	17	180	2	30	0	0	19	210
EndoVac (2)	73	210	10	30	0	0	83	240
Canal CleanMax (3)	17	180	2	30	~102*	90	~121*	300

* Delivered volume variable and approximated from mean values (Table III)

TABLE III

Calculation of approximate mean volume (mL) of sterile water delivered by the Canal CleanMax over a 30-second time interval

	Trial Number	Volume (mL) Delivered	Reservoir of Dental Unit
Canal CleanMax	1	38	< 25% Full
	2	34	
	3	35	
	4	34	
	5	34	
	6	33	
	7	34	> 75% Full
	8	39*	
	9	37	
	10	33	
	11	30	
	12	30*	
	Mean Volume = 34 mL		

* Highest and lowest volumes were excluded prior to acquiring mean.

TABLE IV

Intra-examiner repeatability of examiner 1 (JB) and examiner 2 (SB)

		Second					
Examiner	**First**	**1**	**2**	**3**	**4**	**Kappa**	**Weighted Kappa**
1 (JB)	1	65	2	0	0	**0.61**	**0.75**
	2	28	21	0	0		
	3	0	15	30	1		
	4	0	0	3	15		
2 (SB)	1	46	13	1	0	**0.57**	**0.74**
	2	4	20	10	2		
	3	3	7	11	13		
	4	0	1	3	46		

TABLE V

Inter-examiner agreement between examiner 1 (JB) and examiner 2 (SB)

	Examiner 2 (SB)					
Examiner 1 (JB)	**1**	**2**	**3**	**4**	**Kappa**	**Weighted Kappa**
1	53	11	3	0	**0.42**	**0.62**
2	7	19	18	5		
3	0	5	13	28		
4	0	1	0	17		

TABLE VI

Comparison of mean debris/smear layer scores at coronal (B), middle (A), apical (C), and combined sections of all specimens for Group 1 (control), Group 2 (EndoVac), and Group 3 (Canal CleanMax)

Location	Group	N	Mean	SD	SE	Pairwise* vs. Coronal	Pairwise* vs. Middle	Overall p-value
Coronal (B)	Control (1)	20	2.5	1.2	0.3			0.033
	EndoVac (2)	20	1.6	0.8	0.2	0.0119		
	Canal CleanMax (3)	20	2.2	1.2	0.3	0.3965	0.1196	
Middle (A)	Control (1)	20	2.1	1.2	0.3			0.388
	EndoVac (2)	20	1.6	0.9	0.2	0.2393		
	Canal CleanMax (3)	20	2.0	1.1	0.2	0.8971	0.1196	
Apical (C)	Control (1)	20	2.9	1.2	0.3			0.862
	EndoVac (2)	20	2.9	1.2	0.3	0.8980		
	Canal CleanMax (3)	20	2.8	1.1	0.3	0.6492	0.6642	
Combined	Control (1)	60	2.5	1.2	0.2			0.087
	EndoVac (2)	60	2.0	1.2	0.1	0.0326		
	Canal CleanMax (3)	60	2.3	1.2	0.2	0.4019	0.1663	

* Only relevant if overall p-value is significant.

TABLE VII

Comparison of mean debris/smear layer scores between
Group 1 (Control), Group 2 (EndoVac), Group 3 (Canal CleanMax),
and all groups combined at each location of all specimens

Group	Location	N	Mean	SD	SE	Pairwise* vs. Coronal	Pairwise* vs. Middle	Overall p-value
Control (1)	Coronal (B)	20	2.5	1.2	0.3			0.0703
	Middle (A)	20	2.1	1.2	0.3	0.2120		
	Apical (C)	20	2.9	1.2	0.3	0.2917	0.0298	
EndoVac (2)	Coronal (B)	20	1.6	0.8	0.2			0.0004
	Middle (A)	20	1.6	0.9	0.2	0.9627		
	Apical (C)	20	2.9	1.2	0.3	0.0015	0.0021	
Canal CleanMax (3)	Coronal (B)	20	2.2	1.3	0.3			0.0794
	Middle (A)	20	2.0	1.1	0.2	0.5889		
	Apical (C)	20	2.8	1.1	0.3	0.1459	0.0329	
Combined	Coronal (B)	60	2.1	1.2	0.1			<0.0001
	Middle (A)	60	1.9	1.1	0.1	0.2812		
	Apical (C)	60	2.9	1.1	0.1	0.0006	<0.0001	

* Only relevant if overall p-value is significant.

DISCUSSION

The purpose of this study was to determine the *in-vitro* effectiveness of root canal debridement after irrigation and aspiration via EndoVac compared to Canal CleanMax following hand and rotary instrumentation. Based on the results of this investigation, the EndoVac system produced a statistically significant enhancement in removal of debris and smear layer from the coronal one-third of root canal walls as compared with the control. EndoVac showed no significant difference when compared with the Canal CleanMax (FIGURE 76 and TABLE VI). No significant differences were found between any of the groups in the middle or apical one-third of root canals (FIGURE 76 and TABLE VI). One possible explanation could be attributed to the design of the Master Delivery Tip (MDT) of the EndoVac system as well as the design of the root canal preparation (FIGURE 41). The MDT delivers irrigation solution at the most coronal aspect of the access opening while also evacuating fluid and debris. It is speculated that a "whirlpool" effect is created in the coronal aspect of the canal, increasing turbulence and possibly enhancing debridement efficacy. According to Boutsikis,[202] development of turbulent flow leads to more efficient replacement of irrigation solution. This may also aid in the removal of smear layer from dentinal tubules by actively manipulating EDTA while it chelates calcium from the dentinal tubules. Since the irrigation needle of the MDT rests immediately inside the access opening, irrigation solution is limited to the coronal aspect of the canal throughout irrigation. This differs from the control group and the Canal CleanMax groups, which both utilize Monoject syringe irrigation with 30-

gauge ProRinse needles that approximate the working length of the canal. The tapered design of the root canal preparation also allows for more fluid exchange at the coronal aspect, where the MDT is positioned.

When debris/smear layer scores in locations were compared, the apical third of the control group, the EndoVac group, and Canal CleanMax groups all exhibited more residual debris/smear layer as compared to coronal and/or middle thirds (FIGURE 77 and TABLE VII). Also, when all groups were combined, both coronal and middle thirds of specimens were cleaner than apical thirds (FIGURE 77 and TABLE VII). Lastly, there were no significant differences in debris/smear layer scores between groups in the apical third of root canals. In fact, the debris/smear layer scores for the control group, EndoVac group, and Canal CleanMax group exhibited the least amount of numerical difference compared to other locations within the root canal system (FIGURE 77 and TABLE VII). This supports the multiple studies that have suggested that bacteria and debris remain within the root canal system, specifically in the apical one third, even after meticulous chemo-mechanical debridement.[23-26, 30, 36-38, 40-43, 277-279] Endodontic instruments are unable to plane all walls of the complex root canal system, and sodium hypochlorite is unable to dissolve tissue from these uninstrumented areas.[23-26, 159] Also, the coronal and middle thirds of the root canal wall are more susceptible to the effects of chelating agents such as EDTA mainly due to limitations in access of solution, reduction of size and density of dentinal tubules, and sclerosis of dentinal tubules in the apical aspects of the root canal system.[194, 261-264]

When all locations were combined the EndoVac produced marginally significant cleaner root canal walls when compared to the control group, but no significant

difference when compared to the Canal CleanMax group (FIGURE 76 and TABLE VI). This supports other studies in which the EndoVac system proved superior in debridement and disinfection of the root canal system as compared to standard needle irrigation.[44, 46, 292] However, these studies largely focused on the EndoVac's enhanced debridement and/or disinfection of the apical aspect of the root canal system. Our study did not suggest any significant enhancement in apical cleanliness of root canals irrigated with the EndoVac system. Also, even though our study was powered based on smaller standard deviations than were observed and is thus underpowered to detect differences, pairwise comparisons based on marginal overall significance should be viewed with caution since no adjustments were made for multiple comparisons.

Human canines were chosen for experimentation due to expected straight canals with round, tapering anatomy in apical one-third.[336] The relatively straight and round canal system was thought to have allowed for more consistent canal preparations and optimal sectioning. Also, only teeth in which a #30 K-file could not pass through the apical foramen were selected (FIGURE 4) since the average apical foramen diameter of anterior teeth is expected to be between 0.3 and 0.5 milimeters.[140] This would allow for creation of a precise and consistent "apical stop" since canals would be instrumented to an apical diameter of 0.5 mm. This consistency in canal preparation and size would seemingly allow for more of a direct comparison of irrigation methods. However, the strict selection criteria may have hindered the clinical validity of the study, since a large number of root canals possess a wide variety of curvatures and anatomic anomalies. [3, 27-30] Also, experimental teeth were de-coronated (FIGURE 6) prior to instrumentation in attempt to standardize samples. However, the coronal aspect of teeth may provide

variable pulp chamber anatomy and limit access size and shape which may impair the actual function and efficacy of the tested irrigation systems in a clinical setting.

Final rotary instrumentation with a ProTaper F5 file was chosen to create an apical diameter of approximately 0.5 mm at the working length (FIGURE 26). The ProTaper files exhibit a variable tapered design, which makes calculation of diameters coronal to the tip relatively impossible. However, it was thought to have been large enough to plane the periphery of the canal wall in all aspects, creating a more round preparation without compromising peri-cervical dentin.[174, 176, 177] Also, the 0.5 mm apical diameter at working length with coronal preparation of relatively large taper should have allowed for close approximation of the 30-gauge (0.301 mm) ProRinse needle (FIGURE 10), the 0.55 mm-diameter EndoVac MacroCannula (FIGURE 45), and the 0.32 mm-diameter EndoVac MicroCannula (FIGURE 49).[48, 175-178, 324] Also, the 0.6 mm-diameter insert-tube of the Canal CleanMax theoretically should have approximated the 0.5 mm diameter working length by 1.5 mm to 2.0 mm due to the relatively large taper of the canal (FIGURE 59).[54, 175-178] Canal preparation diameters large enough to maximize debridement efficacy of instrumentation and allow for close approximation of all irrigation devices to working length was chosen to allow for optimum performance of each irrigation group.[3, 27-29, 183-185,3, 183-185, 280-282] However, this should be considered when interpreting results, as clinically not all root canals will accommodate preparations of such large apical diameter and coronal flare.[187]

The ProTaper rotary file system was chosen for experimentation for several reasons (FIGURE 22). First, the ProTaper system is relative popular among general dentists and endodontists alike, mainly due to its simplicity and efficiency.[174-179] In fact,

Yun and Kim[180] showed that the ProTaper system created acceptable shapes in significantly less time than GT rotary, ProFile, and Quantec instruments. Also, in cross-section, the ProTaper file exhibits sharp, triangular cutting edges and absence of radial lands that greatly enhances cutting efficiency and flexibility.[1, 174, 176-178] Jeon et al. showed that instruments with more active blades tend to shear dentin during cutting, producing a thin superficial layer of smear compared with the thicker, deep-penetrating smear layer produced by U-shaped blades.[300, 301] Smear- layer production was attempted to be minimized during instrumentation to realistically simulate an optimal clinical scenario so that irrigation techniques could be objectively compared.

Since Yun and Kim[180] showed that deformation of ProTaper files was significantly increased as compared to GT rotary, ProFile, and Quantec instruments, each file was only used to instrument five canals prior to discarding. This number of uses was chosen in order to simulate clinical practice by maintaining optimal cutting efficacy of the instrument, minimizing the likelihood of file separation, and minimizing overhead expenses. No files were separated during any portion of experimentation.

Each ProTaper nickel-titanium rotary file was coated with ProLube root canal conditioner prior to insertion into the root canal of all specimens as suggested by the manufacturer (FIGURE 24).[176] ProLube contains 15-percent EDTA, 10-percent carbamide peroxide, and polyethylene oxide.[337, 338] The manufacturer of ProLube suggests that the EDTA chelates calcium salts from calcified areas within the root canal aiding in instrumentation. Also, it is suggested that the EDTA opens the dentinal tubules which allows for penetration of other medicaments used in endodontic therapy. The manufacturer also suggests that oxygen bubbling from the carbamide peroxide facilitates

the removal of pulp tissue, dentinal shavings, and debris. Lastly, the polyethylene oxide is a water soluble base that produces the gel consistency of ProLube. The manufacturer suggests this additive acts as a lubricant to facilitate cleaning and shaping of the root canal system during instrumentation.[337] Gel-based lubricants have been shown to reduce frictional resistance and torsional load during instrumentation of curved root canals with nickel-titanium rotary instruments.[339]

The irrigation solutions chosen for experimentation were 6.0-percent sodium hypochlorite in the form of Clorox and 17-percent ethylenediaminetetraacetic acid (EDTA) in the form of SmearClear (FIGURE 35). Multiple authors have suggested maximized removal of debris and smear layer from the walls of root canals by alternating solutions of sodium hypochlorite and EDTA.[35, 256, 265] Sodium hypochlorite was also chosen because of its profound antimicrobial activity, property to dissolve vital and necrotic tissue, lubricating action, low cost, availability, and popularity.[1, 3, 25, 197-199] An undiluted solution of 6.0-percent sodium hypochlorite was chosen due to previous studies showing that increasing the concentration of sodium hypochlorite will result in a relative increase in tissue dissolution and antimicrobial effect compared to a lower concentration at the same pH.[213-217] Also, Clegg et al.[229] showed that only 6.0-percent sodium hypochlorite was capable of removing bacteria and biofilm from root canals when compared to lesser concentrations of sodium hypochlorite and chlorhexidine.

SmearClear was chosen due to the presence of a cationic surfactant called cetrimide and proprietary anionic surfactant(s) in addition to the 17-percent EDTA.[257, 266] Ethylenediaminetetraacetic acid (EDTA) is a common chelating agent used in the irrigation of root canals during endodontic therapy due to its ability to remove smear

layer, specifically at a concentration of 17-percent.[194, 254-258] Cetrimide is a quaternary ammonium compound and a cationic detergent.[266] It readily lowers the surface tension of a liquid, which may improve access and flow of solution into areas of impeded access, such as the apical extent of narrow root canals.[268, 271, 272] In addition cetrimide may alter the mechanical stability of biofilm by weakening the cohesive forces, and disrupting its self-produced extracellular polymeric substance (EPS) matrix.[268, 270] It has also been shown that the addition of surfactants may allow for increased penetration of irrigation solution into dentinal tubules during instrumentation.[273] In theory, this should have enhanced debridement efficacy with more efficacious removal of smear layer.[255]

The solution of 17-percent EDTA (SmearClear) was allowed to sit undisturbed in all root canals for one minute after delivery and prior to final irrigation with 6.0-percent sodium hypochlorite for 30 seconds. One minute was chosen to maximize the potential for smear layer removal while minimizing dentinal erosion. Multiple studies have suggested EDTA possessing long-lasting residual demineralization effects leading to deleterious erosion of peritubular and intratubular dentin.[194, 256, 258, 265, 276] Calt and Serper[258] showed that smear layer was as effectively removed from root canal walls by irrigation with 17-percent EDTA for one-minute and ten-minute intervals followed by irrigation with 5.0-percent sodium hypochlorite. However, excessive peritubular and intratubular erosion was observed only in the root canals irrigated for 10 minutes with 17-percent EDTA. Saito et al.[254] observed similar findings in root canals irrigated with 17-percent EDTA for 10 minutes followed by 6.0-percent sodium hypochlorite. It was also observed that decreasing the irrigation time with 17-percent EDTA to 30 or 15 seconds, significantly decreased the efficacy of smear layer removal as compared to irrigation with

17-percent EDTA for one minute. The authors recommended that root canals be irrigated with a final rinse of 17-percent EDTA for one minute followed by 6.0-percent sodium hypochlorite with solutions being delivered with a 28-gauge or 30-gauge side-vented needle placed 1 mm from working length.

Irrigation in the control and Canal CleanMax groups was performed with a standard 12-ml Monoject syringe with a 30-gauge, ProRinse side-vented, closed-end, closed-end needle for several reasons (FIGURE 8). The 30-gauge needle coincided with a diameter of approximately 0.305 mm (FIGURE 10), which closely approximated the 0.32 mm-diameter of the EndoVac MicroCannula (FIGURE 49).[48, 49, 324] Also, Druttman et al.[279] showed that only a 30-gauge needle completely cleared the dye from the apical aspect of a simulated root canal. This diameter also allowed for easy placement of the needle within approximately 1 mm from the working length in the tapered root canals that were prepared to an approximate apical diameter of 0.5 mm with the ProTaper F5 file.[176-178] The ProRinse needles were placed to a level 1 mm from the working length due to numerous studies suggesting that irrigation of the root canal is limited to approximately 1 mm beyond the irrigation tip.[183, 200-202, 279] The ProRinse side-vented, closed-end needle was chosen for several reasons (FIGURE 10). First, according to Desai and Himel[291] irrigation with a side-vented, closed-end needle via positive pressure within 2-mm to 3-mm working length is the most commonly used irrigation system. Second, Vinothkumar et al.[287] showed that irrigation with single side-vented, closed-end needles exhibited enhanced efficacy as compared to double side-vented, and hypodermic needles. Third, the side-vented, closed-end design has been recommended for use clinically to minimize the risk of apical extrusion of irrigation solution, specifically

sodium hypochlorite.[218, 288] Lastly, previous studies by Neilsen/ Baumgartner[44] and Shin[315] comparing the debridement efficacy of the EndoVac system to standard needle irrigation implemented 30-gauge, side-vented, closed-end needles.

Despite the manufacturer of the EndoVac recommending loading 20-ml syringes with sodium hypochlorite and 3-ml syringes with EDTA, graduated 12-ml Monoject syringes were used for all irrigation solutions in all groups (FIGURE 8 and FIGURE 41)[47-50] During preliminary trials using a 20-ml Monoject syringe loaded with the Master Delivery Tip, it was determined that approximately 12 ml of sodium hypochlorite was consistently delivered over 30 second intervals (FIGURE 33 and TABLE I). The manufacturer of the EndoVac did not recommend delivering irrigation solution for more than 30 seconds at point in irrigation of root canals.[47-50] Also, the smaller syringes are less cumbersome and more practical for clinical used during endodontic therapy. It was also assumed that 12-ml syringes are probably the largest syringe used by the majority of practitioners. Overall, choosing the 12-ml syringe for all irrigation groups and irrigation solutions provided a method of standardization between groups, and allowed for more accurate quantitative determination of the volume of irrigation solution delivered.

The volume of irrigation solution that was delivered during various stages of the irrigation process in each group was standardized by a pilot study (FIGURE 33 and TABLE I). Volumes were standardized in an attempt to minimize variability and eliminate possible advantages or disadvantages provided to either device by variation in methods. The manufacturers and inventors of the EndoVac and the Canal CleanMax both recommend final irrigation regimens to be performed for a time interval of thirty seconds. Thus, the amount of solution to be delivered after instrumentation was

determined by calculating the average volume of 6.0-percent sodium hypochlorite and 17-percent ethylenediaminetetraacetic acid (EDTA) delivered by a standard 12-ml Monoject syringe equipped with a 30-gauge ProRinse, side-vented, closed-end needle or the Master Delivery Tip of the EndoVac system over thirty-second intervals (FIGURE 34). During manual instrumentation, 1 ml of sodium hypochlorite was arbitrarily chosen as a realistic amount of irrigation solution to be delivered between file transitions (FIGURE 9). Calculations from the pilot study indicated a required duration of approximately 10 seconds to deliver 1 ml of sodium hypochlorite with a standard 12-ml Monoject syringe equipped with a 30-gauge ProRinse, side-vented, closed-end needle (FIGURE 33 and TABLE I). Thus, the amount of solution to be delivered during instrumentation was determined by calculating the average volume of irrigation solutions delivered over 10-second intervals with standard 12-ml Monoject syringes equipped with 30-gauge ProRinse, side-vented, closed-end needles and Master Delivery Tips of the EndoVac system (FIGURE 33, FIGURE 34, and TABLE I). In reality, this is probably more time spent delivering irrigation solution between instrument transition than realistically expected in a clinical setting. However, all attempts were made to provide the "best-case" scenario for each study group.

Standardization between groups was attempted to minimize variables and eliminate possible advantages or disadvantages provided to either device. "Constant and maximum force was attempted to be placed on the Monoject plunger during expression" of irrigation solutions during the pilot study and experimentation. Maximum pressure was applied in an attempt to maximize consistency of volume of irrigation solution delivered over specific time intervals. In theory, the small diameter of the ProRinse

needle and the Master Delivery Tip would limit the rate and volume of irrigation solution delivered once a threshold pressure was applied to the plunger of the Monoject plunger. However, this theory relies on assumptions that may not be accurate. The ability of the examiner to consistently apply "constant and maximum force" to the Monoject plunger is questionable. Also, even if accomplished, the force applied may not be enough to overcome the theoretical flow rate threshold applied by the limiting needle diameters. Thus, volume of irrigation solution delivered over specific time intervals may have fluctuated, especially as the examiner became manually fatigued. Also, minor debris or manufacturer imperfections within the syringes and/or irrigation needles may have also affected flow rate, which in turn would affect volume of irrigation solution delivered. During the pilot study, these factors would have affected the calculated mean volume of solutions to be delivered over specific time intervals during experimentation. During experimentation these factors would have affected the duration of irrigation solution delivery since the volume delivered was a constant calculated from the pilot study. Also, the calculated volumes of irrigation solutions to be utilized during experimentation were averages calculated from approximate volumes delivered during trial runs in the pilot study. These approximate volumes of the trial runs were intentionally rounded up or down to the closest 0.2 ml according to the measurements provided on the Monoject syringe (FIGURE 8). These intentional approximations were implemented to adjust for fluctuations in consistency of flow rate between trials, provide for ease of calculation of mean volumes, and to provide whole-number volumes. The whole-number volumes could theoretically be more realistically replicated during experimental irrigation delivery. However, the accuracy and precision of the measurements on the multiple

Monoject syringes utilized, the ability of the examiner to accurately and precisely quantify the volume measurements on the Monoject syringes, and ability of the examiner to accurately and precisely deliver exact volumes of irrigations solutions was not validated. Also, although the same online timer tool was utilized during the pilot study, it was impossible to start and stop the delivery of irrigation solution at the exact moment the timer started and stopped (FIGURE 34). Overall, the volume of irrigation solution delivered over specific time intervals by each study group was standardized. However, it should be stressed that the volumes of irrigation solutions determined to be delivered during experimentation via the pilot study, the calculated total volumes of irrigation solutions delivered, and the duration of irrigation solutions are approximations. Moreover, even if "constant and maximum force" applied to the Monoject syringe plunger did provide accurate and consistent volumes of irrigation solution delivered over specific time intervals, this practice has minimal realistic clinical applicability. Maximizing pressure of irrigation solution delivered most likely increases the risk of apical extrusion of irrigation solution, which could to detrimental health effects and toxicity to host cells.[203-209]

After the pilot study was performed, volumes of 6.0-percent sodium hypochlorite and 17-percent EDTA to be delivered in each group was determined so that the same amount of time would be spent irrigating all root canals in each irrigation group (FIGURE 33 and TABLE I). Although attempts were made to standardize the volume of each irrigation solution delivered as well as the duration of irrigation solution delivery between each study group, a miscalculation occurred in the design of the study. The manufacturer of the EndoVac recommended that after final instrumentation, root canals

should be irrigated with 6.0-percent sodium hypochlorite for 30 seconds with the MacroCannula followed by 30 seconds with the MicroCannula.[47-50] These recommendations would yield a total of 60 seconds of irrigation with 6.0-percent sodium hypochlorite in the EndoVac group after final instrumentation. However, the added irrigation time with 6.0-percent sodium hypochlorite via the MicroCannula of the EndoVac was not appropriately compensated in the control and Canal CleanMax groups. The miscalculation was realized upon initiating irrigation of root canals in the EndoVac group. Unfortunately, root canals of the control group had already been completely irrigated with 6.0-percent sodium hypochlorite and 17-percent EDTA. Thus, each root canal of the EndoVac group received approximately 30 additional seconds of irrigation with 4 ml of 6.0-percent sodium hypochlorite prior to irrigation with 17-percent EDTA (FIGURE 39 TABLE II). The additional volume and time of irrigation with 6.0-percent sodium hypochlorite most likely provided the EndoVac group with an unfair advantage as compared to the other groups, and this should be considered when interpreting results.

Total volumes of irrigation solutions utilized in irrigation of samples in the EndoVac group dwarfed that of samples from the control and Canal CleanMax groups (FIGURE 39 and TABLE II). Approximately 73 ml of 6.0-percent sodium hypochlorite was delivered over approximately three minutes and thirty seconds in the EndoVac group compared with only 17 ml of 6.0-percent sodium hypochlorite delivered over three minutes in the control and Canal CleanMax groups (FIGURE 39 and TABLE II). The EndoVac also delivered approximately 10 ml of EDTA over a period of approximately 30 seconds compared with 2 ml delivered in the control and Canal CleanMax groups over a period of 30 seconds (FIGURE 39 and TABLE II). Total volume of 6.0-percent

sodium hypochlorite and 17-percent EDTA delivered during entire irrigation regimen was recorded (FIGURE 39 and TABLE II). The Canal CleanMax also delivered sterile water from the dental unit for 30-second intervals after final irrigation protocol with 6.0-percent sodium hypochlorite and 17-percent EDTA. The average amount of sterile water delivered from the dental unit by the Canal CleanMax over 30 second intervals was determined (FIGURE 66 and TABLE III) to approximate the total volume of sterile water delivered by the Canal CleanMax during experimentation (FIGURE 39 and TABLE II). The approximate total volume of sterile water delivered by the Canal CleanMax during experimentation was 102 ml. This yielded a total of approximately 121 ml of all irrigation solutions delivered during irrigation with the Canal CleanMax (FIGURE 39 and TABLE II).

The average amount of sterile water (34 ml) delivered from the dental unit by the Canal CleanMax over 30 second intervals was determined (FIGURE 66 and TABLE III) to approximate the total volume of sterile water delivered by the Canal CleanMax during experimentation (FIGURE 39 and TABLE II). Unfortunately, the volume of sterile water delivered by the Canal CleanMax during trial runs fluctuated from 30 ml to 39 ml, seemingly dependent on the water level of the dental unit reservoir (TABLE III). Although, these two values were discarded prior to calculating the approximate mean of 34 ml delivered during irrigation, there was no way to quantify or standardize the amount of sterile water actually delivered during experimentation. Also, the volumes of the trial runs were approximated and intentionally rounded up or down to the nearest milliliter of the graduated cylinder (FIGURE 66). The intentional approximations revolved around the large fluctuation in volume of sterile water delivered during each trial and to facilitate

ease of calculation. In addition, the transfer of sterile water from the beaker to the graduated cylinder most likely decreased the accuracy of volume determination (FIGURE 66). More importantly, the analog clock used for determination of when to start and stop irrigation with the Canal CleanMax during the trials and experimentation was less than ideal at determining accurate and precise 30-second intervals (FIGURE 65 and FIGURE 66). Even if the foot pedal of the dental rheostat was started and stopped at the precise moment, the Canal CleanMax exhibited delays in initiation and cessation of sterile water delivery from the dental unit. Thus, the calculation that approximately 102 ml of sterile water was delivered during experimentation using 34 ml as a constant amount delivered over each 30-second irrigation interval is likely an invalid assumption.

The superior rate and volume of sodium hypochlorite solution delivered with the EndoVac system may have contributed to its enhanced debridement efficacy observed in the coronal third and in combined thirds of all specimens (FIGURE 39 and TABLE II). Sodium hypochlorite dissolves necrotic tissue and organic debris by breaking down proteins into amino acids.[213-217] It provides continuous tissue dissolution under the condition that free chlorine is available in solution. This free chlorine is depleted during the tissue dissolution requiring frequent replenishment of sodium hypochlorite [1, 147, 213-217, 228] Multiple authors have published studies in which root canal debridement efficacy was enhanced by increasing the volume of sodium hypochlorite delivered.[37, 284] Although outside the scope of our study, the increasing volume of sodium hypochlorite delivered by the EndoVac may also contribute to an enhanced microbial effect. In fact, Sedgley showed that 6 ml of sodium hypochlorite is significantly more effective than 3 ml at removing labeled bacteria in root canals.[283] Lastly, the increased flow and volume of

solution delivered facilitates the removal and evacuation of debris from the root canal system.[1-3]

The effects of increased volume of EDTA delivered during irrigation with the EndoVac are unknown. However, the abundance of solution may facilitate continuous and maximal dentinal chelation. During the demineralization of dentin by EDTA, calcium is exchanged from the dentin by hydrogen. The resultant release of acid causes protonation of EDTA inhibiting its demineralization effect on dentin over time. Over time, acid accumulates and protonation of EDTA prevails leading to decrease in rate and eventual cessation of demineralization. Theoretically, dentin demineralization is ended when all available ions have been bound.[194, 275] Thus, providing a continuous, large quantity of EDTA may allow for maximum chelation and smear layer removal. Again, the increased flow and volume of solution delivered facilitates the removal and evacuation of debris from the root canal system.[1-3] However, the actual benefit of enhanced flow and volume of EDTA delivered over a 30 second period by the EndoVac is unknown, and may be enough to justify the inflated cost of excess solution.

The Canal CleanMax delivered the most solution (~121 ml) to the root canal system during irrigation (FIGURE 39 and TABLE II). However, sterile water accounted for the approximate 102-ml difference between total irrigation solutions delivered by the control group (19 ml) and for the approximate 38-ml difference delivered by the EndoVac group (83 ml). Sterile water was delivered from the dental unit by the Canal CleanMax to root canals for 30 seconds after each 30-second delivery of 6.0-percent sodium hypochlorite and 30-second delivery of 17-percent EDTA with the Monoject syringe with ProRinse needle (FIGURE 65). The Canal CleanMax simultaneously

delivered sterile water from the dental unit while aspirating canal contents via negative pressure but relied on the Monoject syringe with a ProRinse needle to deliver 6.0-percent sodium hypochlorite and 17-percent EDTA prior to its negative irrigation (FIGURE 8 and FIGURE 65). The Canal CleanMax can simultaneously deliver multiple types of irrigation solutions while aspirating, but requires the addition of a "multiple reservoir irrigation unit (FIGURE 78)."[51, 53, 54] Upon consultation with the inventor and manufacturer, it was determined that the additional irrigation unit is not necessary to maximize efficacy.[54] This superior volume of irrigation solution delivered by the Canal CleanMax could be perceived as an advantage due to more time and total volume of irrigation solution delivered to the root canal system (FIGURE 39 and TABLE II). However, no volume of sodium hypochlorite or EDTA was added during irrigation, and it is unlikely that sterile water enhanced debridement efficacy.

The apices of all teeth were sealed with sticky wax and the external root surface was sealed with vinyl-polysiloxane adhesive (VPS) adhesive and VPS impression material to simulate a "closed system" (FIGURE 15, FIGURE 16, FIGURE 17, FIGURE 18, and FIGURE 19). Similar methods have been proposed by other authors,[44, 46, 256] and the exact method described was agreed upon by the inventors of the EndoVac and the Canal CleanMax.[49, 54] The "closed system" is seemingly created to simulate a natural tooth housed in the oral cavity as the root is enclosed by alveolar socket. It has been proposed that in-vivo, the canal acts like a "closed-end channel," with the apex being the closed-end. Thus, gas becomes trapped at the apical extent of the canal during irrigation delivery, which creates a "vapor lock effect."[201, 202, 221, 289] This phenomenon limits the expression of irrigation solution to approximately 1 mm beyond the irrigation tip in a

positive pressure system.[183, 200-202] Therefore, in our study, a 30-gauge, ProRinse side-vented, closed-end needle, was selected for delivery of irrigation solution in the Canal CleanMax and control groups to a level of 1 mm short of the working length (FIGURE 8 and FIGURE 10). The position of the needle relative to the working length was chosen to maximize the debridement potential of irrigation in the control and Canal CleanMax groups as compared to the EndoVac group in which the MicroCannula was progressed to the actual working length. Progressing the ProRinse needle to working length would have most likely enhanced debridement efficacy in our study. However, this practice may lead to apical extrusion of irrigation solution clinically, which would equate to chemical induced periradicular tissue destruction. [205-209] Clinically, it is possible for apical extrusion of irrigation solution even in a closed system, but the risk is significantly increased in roots that exhibit open apices or in the event that the irrigation needle binds, especially in close proximity to the apex.[203-209] The EndoVac system has been shown to exhibit superior safety over standard positive pressure needle irrigation and other methods by minimizing apical extrusion of irrigation solution.[291] Our study did not directly evaluate amount of irrigation solution extruded beyond the apices of root canals by any irrigation method.

In 2010 Tay et al.[289] compared remaining debris and smear layer along the walls of root canals of extracted teeth in open versus closed systems after irrigation with a positive pressure side-vented needle delivery system. Micro-CT scans of fluid filled canals resulted in a "vapor lock" present in the closed system which prevented fluid from travelling beyond the apical 0.5 mm to 1 mm of the root canal. The open system did not display a "vapor lock," and fluid was able to travel to the most apical extent of the canal.

SEM analysis also revealed a statistically significant reduction in debris in the open system at the coronal, middle, and apical segments of the root canal. The authors concluded that *in-vitro* studies evaluating debridement efficacy of root canals in which "open systems" are designed should be interpreted with caution.

The idea of a perfectly sealed, "closed system" existing *in vivo* may be unrealistic due to inability to account for multiple variables that may influence the hydrodynamics of the canal, including but not limited to presence of intact cementum, periodontal disease, periapical lesion, sinus tract, variable tissue pressures, etc. The simulated "closed system" most likely maximizes the efficacy and safety of a negative pressure system irrigation/aspiration system, and must also be considered when interpreting results of *in-vitro* studies.

Despite anecdotal reports, irrigation with the EndoVac system was relatively simple once the parts were assembled, which was neither difficult or time intensive (FIGURE 40, FIGURE 41, FIGURE 43, FIGURE 44, FIGURE 47, FIGURE 48, FIGURE 52, and FIGURE 53). In addition, the manufacturer of the EndoVac has introduced the multiport adapter, which they suggest reduces the amount of tubing, removes tubing from the patient, and provides a place to hang the components of the EndoVac system (FIGURE 79).[49] The Master Delivery Tip (MDT) facilitated a rapid and efficient replenishment of irrigation solution to the coronal aspect of the root canal system while simultaneously aspirating liberated debris and excess solution (FIGURE 41, FIGURE 43, FIGURE 47, FIGURE 52, and FIGURE 53). The MDT exhibited deficient ability to evacuate overloaded irrigation solution within access opening during continuous irrigation. Clinically, this could lead to spilling of irrigation solutions onto

rubber dam which if not sealed properly could leak into the oral cavity, adjacent hard and soft tissues, or onto patient's clothing. The manufacturer recommends to "double-bib" the patient prior to treatment. One possible explanation for the "overfilling," could be attributed to the inability to abide by manufacturer's recommendation to," never place the MDT's delivery tip closer than 5 mm from the coronal opening of any pulp canal."[47-50] This was rather impossible to achieve since teeth were decoronated. Although the MDT never clogged during irrigation, one tip was clogged out of the package. The manufacturer recommends poking the opening of the metal lumen with a hand instrument (such as a K-File). All attempts were unsuccessful, but the warranty provided by the manufacturer allowed for replacement of the MDT.[47-50]

Evacuation of irrigation solution from the root canal space was readily accomplished with the MacroCannula and MicroCannula of the EndoVac system (FIGURE 47, FIGURE 52 and FIGURE 53). There have been anecdotal reports of instances in which the cannulae become clogged during irrigation. During our experiment, clogging was not experienced with the usage of the MacroCannula or MicroCannula. However, during clinical usage, the author has experienced clogging of both devices on a relatively frequent basis. According to the manufacturer, one proposed mechanism of clogging is, "skipping or deviating" from the outlined directions for use.[47-50] Inadequate frequency of irrigation and inadequate amount of irrigation solution introduced into the root canal system during the various stages of chemomechanical debridement may also increase the likelihood of cannulae clogging as liberated debris may not be adequately evacuated. In the event of clogging, the manufacturer recommends to blow air into the Luer end of the MacroCannula or MicroCannula with

the dental three-way syringe.[47-50] The author has experienced success clinically de-clogging the system with this method. Clogging of the cannulae out of the package was not noted during experimentation, but is covered by the manufacturer's warranty.[47]

Irrigation and evacuation with the Canal CleanMax was less cumbersome than the EndoVac and required less time for assembly (FIGURE 54, FIGURE 55, and FIGURE 65). The design and form of the handpiece mimics that of a standard dental handpiece, facilitating clinician comfort and familiarity (FIGURE 54 and FIGURE 55). A high level of negative pressure is generated by the Canal CleanMax because it utilizes the compressed air from the dental unit. A standard high speed handpiece is first connected to the dental unit, and air pressure to the system is adjusted to 35 pounds per square inch as recommended by the manufacturer (FIGURE 63). The high speed handpiece is then replaced with the Canal CleanMax. The level of negative pressure can be adjusted by the "power control ring" on the base of the handpiece (FIGURE 57).[51, 53, 54] However, the ring was set to allow for the maximum amount of negative pressure so that ultimate debridement efficacy of the device could be evaluated. A wide stream of high pressure mist was evacuated from the exhaust vent on the head of the handpiece during irrigation/aspiration, which could not be effectively evacuated by the high power suction from the dental unit (FIGURE 65). Clinically, this could lead to negative sequelae if irrigation solutions are forced into oral cavity, anatomic structures of the head and neck, or onto patient's clothing. Also, the effect of such high negative pressure to periapical tissues should be questioned, because the manufacturer indicates a possibility that "damage on apical tissue by suction pressure may occur."[51, 53, 54] Future studies should focus on safety of the system.

During experimentation several other concerns revolving around the use of the Canal CleanMax arose. The insert tubes would often detach from the handpiece while irrigating/aspirating. This was attributed to the negative pressure between the insert tube and the canal wall exceeding that of the insert tube and connection to the handpiece. This led to further questioning of a need for such high negative pressure, as it may cause periapical contents to be pulled into the canal system immediately prior to obturation. Lastly, it seemed strange that the Canal CleanMax uses the standard dental line to deliver "sterile" water to the canal system during irrigation and aspiration. The biggest area of concern hinders on the delivery of sodium hypochlorite and EDTA relying on an additional source, such as the Monoject syringe with ProRinse needle used in our study. Given the manufacturer illustrates the irrigation solution being added to the canal system via syringe prior to irrigation and aspiration with the Canal CleanMax system, the "sterile" water from the dental unit should be the final solution exposed to the root canal system.[51, 53, 54] Unfortunately, water from the dental unit has been shown to harbor a diverse microflora of bacteria, yeasts, fungi, viruses, protozoa, unicellular algae and nematodes most likely as a result of stagnation within the narrow-bore water line tubing.[340] Even in the event that the Canal CleanMax rendered the canal wall free of debris and smear layer, it may be actually introducing microorganisms into the root canal system. Future studies should be directed at determining differences in microorganism quality and quantity in root canals before and after irrigation with the Canal CleanMax system. A major objective of root canal therapy is to remove canal contents, specifically living, infectious, microorganisms.[9, 21] Thus, the results of these studies help to determine the clinical usefulness of the Canal CleanMax.

One proposed advantage of the Canal CleanMax system over the EndoVac system includes the ability to de-clog the system with the "One-push cleaning system."[54] When the button is pushed, air is ejected from the insert tube and exhaust vent on the head, exhausting the clog (FIGURE 60).[51-54] During experimentation, the insert tubes of the Canal CleanMax system were readily and frequently clogged with debris. However, the "One-push cleaning system" was very easy, fast, and effective. There were no instances in which manual de-clogging was required. Safety of this feature should be further evaluated. There is an obvious risk of forceful extrusion of irrigation solution, debris, or air beyond the apex of the root into periapical tissues upon inadvertent depressing of the button or in the event of a device malfunction. This could lead to serious health complications including but not limited to a sodium hypochlorite accident or air embolism, the former of which likelihood is seemingly already increased due to positive delivery of irrigation solution from head of handpiece directly onto insert tubes (FIGURE 65). Lastly, the insert tubes were often blown off of the handpiece when the "One-push cleaning system" was activated.

Once irrigation protocols were completed, the samples were removed from VPS impression material and prepared for sectioning (FIGURE 67 and FIGURE 68). All roots were then sectioned from mesial-distal because maxillary anterior roots and canals are usually wider bucco-lingually. Also, a root depression often exists on the mesial and distal root surfaces allowing for easier tracing of the root canal from chamber to orifice.[341] A diamond-coated separating disc loaded in a Dremel rotary tool was utilized to incorporate a groove along the long axis of all teeth both on mesial and distal aspects of tooth structure to a depth approximating dentino-enamel junction using care not to

penetrate the canal system with the disc (FIGURE 69). A new surgical chisel was placed within groove and a mallet was used in one forceful, abrupt movement to longitudinally section samples (FIGURE 70). By nature, this technique possesses weaknesses and seemingly incorporates variables into the study that may have unjustly affected results.

The sectioning of human roots with a chisel and mallet is not a debris-free process. Theoretically, it is likely that debris not originally present along root canal walls after instrumentation and irrigation was incorporated into the root canal system and/or imbedded into dentinal tubules during the sectioning process.[30] Furthermore, it is impossible to determine the quantity, quality, or location of iatrogenically incorporated debris during sectioning because the canal walls cannot be analyzed by scanning electron microscope until roots are sectioned. Thus, SEM analysis of root canal walls may not equate to a valid interpretation of actual debridement efficacy of instrumentation and irrigation techniques. Also, it was not possible to incorporate mesial and distal grooves that exhibited precise depths from access to apex. Certain aspects of the canal wall would often fracture uncleanly rather than separate uniformly, or would require multiple attempts with the mallet. Not only would this likely generate more debris or smear layer, it would also leave a less than ideal canal wall for future SEM examination. Also, the sectioning disc and chisel blade used for sectioning are machined straight and consistent, but root canals do not possess either of these characteristics (FIGURE 69 and FIGURE 70). The machined chisel blade cannot accommodate to canal deviations. This is further complicated by the fact that the chisel must be initially placed at the apical foramen since it is the narrowest aspect of the canal and root structure. By placing the blade in this position, any variation in the apical foramen relative to canal position facilitated an

asymmetric sectioning, or worse, a fracture of the most apical segment of the canal system (FIGURE 71). The latter posed the most significant problem because multiple studies have suggested that bacteria and debris remain within the root canal system, specifically in the apical one third, even after meticulous chemo-mechanical debridement.[30, 36-43] Proposed advantages of a negative pressure irrigation system are its ability to safely and effectively debride and disinfect the apical aspect of the root.[44-46] However, the materials and methods presented in this study may not have allowed for predictable and accurate evaluation of the apical one third of the root canal system.

Future studies should attempt to derive a solution to the dilemma of incorporating debris into the root canal system during sectioning of teeth. In 2010, after our experimentation was completed, Jiang et al.[317] described an innovative method to reduce or eliminate the risk of introduced debris during sectioning of extracted teeth. Teeth were embedded into self-curing resin, and sectioned longitudinally with a microtome. Sandpaper was used to abrade the canal-side of the freshly sectioned root halves for ease of reapproximation. The two halves were then reassembled by inserting four self-tapping bolts through holes drilled through the resin blocks. A customized ultrasonic tip was used to implement a standard groove of 4 mm in length, 0.5 mm in depth, and 0.2 mm wide into one half of each root canal 2 mm to 6 mm from the working length. These simulated oval aspects of the apical root canal were filled with dentin debris and sodium hypochlorite mixture to simulate the dentin debris accumulation canal extensions prior to instrumentation. This method allowed for a standardized root canal space and ability to quantify the amount of dentin debris present in the root canal before irrigation. When

root halves were separated and evaluated via stereomicroscope, the reliability of evaluation of dentin debris removal after instrumentation and irrigation was enhanced.

Post-operative root canal cleanliness was evaluated by scanning electron microscope (SEM) analysis as illustrated by numerous studies (FIGURE 74 and FIGURE 75).[6, 30, 35, 193, 251, 254-257, 265, 266, 273, 297, 299, 300, 322, 330] Specimens were desiccated and sputter coated with gold-palladium prior to SEM analysis to enhance specimen conductivity and image sharpness (FIGURE 73).[318-321] According to Hulsmann et al.,[30] SEM analysis of root segments is the standard technique for evaluation of root canal cleanliness. Cleanliness can be further described as the amount of remaining debris and/or smear layer present along root canal walls after instrumentation and irrigation.[30] Debris can be defined as the fragmented remains of dead or damaged cells, tissue, or simply scattered remains of something broken or destroyed.[342] In the canal system this most likely refers to pulp remnants, dentin chips and particles that remain loosely adherent to walls. Smear layer can be defined as a surface film of debris retained on dentin and other surfaces after instrumentation with either rotary instruments or endodontic files; consists of dentin particles, remnants of vital or necrotic pulp tissue, bacterial components and retained irrigant.[7]

Debris and/or smear layer visualized along the walls of the root canal systems was quantified to determine relative cleanliness, allowing comparison of the EndoVac and Canal CleanMax systems (FIGURE 75). Many SEM studies have described a wide variety of scoring systems ranging from three to seven scores.[30] The scoring system used in our study was a hybrid of two previously proposed systems by Hulsmann et al.[6] and Al-Hadlaq et al[322] (FIGURE 75). The hybrid system was created in order to enhance

comprehensiveness of each individual system while maintaining simplicity in order to promote examiner reliability. Upon statistical analysis, it was determined that both intra-examiner and inter-examiner reliability were acceptable, which confirmed the validity of the chosen system (TABLE IV and TABLE V). However, this reliability may also be attributed to the maximization of examiner calibration. The two independent examiners selected for specimen evaluation were participating in similar research projects utilizing similar materials and methods. Both of these individuals had participated as examiners of SEM images of sectioned anterior human teeth at X750 to X1000 magnification with identical scoring criteria. Also, two SEM photographs from their studies that exhibited agreed scoring in each category were included with scoring criteria as a guide for calibration (FIGURE 75).[333, 334]

Various SEM magnifications have been suggested for evaluating root canal cleanliness after instrumentation and/or irrigation.[6, 30, 35, 193, 251, 254-257, 265, 266, 273, 297, 299, 300, 322, 330].[30] The initial proposed design of our experiment called for evaluation of root segments at X200 times magnification and X1000 magnification. The former was thought to allow for evaluation of overall residual debris and/or smear layer along the coronal, middle, and apical segments of the root canal wall. The latter would allow for quantification of patent dentinal tubules in a specific area of the evaluated segments of the root canal wall.[330] However, a previous study by Van,[332] and similar ongoing studies by Barney[334] and Binkley,[333] suggested the use of X1000 magnification. The authors experienced difficulty in discerning differences in amounts of debris/smear layer present along root canal walls and patency of dentinal tubules at magnifications under X1000. The X1000 magnification chosen for experimentation did not come without inherent

disadvantages. Only a small area of the root canal could be observed at the higher magnification. According to Hulsmann,[30] the SEM operator tends to select clean canal areas with open dentinal tubules. Although an independent dental SEM research technician/analyst performed all SEM operations, the innate observer bias makes the realistic interpretation of results difficult, and may question their validity.

The results of our study concerning the EndoVac system do not agree with that of previous authors.[44, 46] In 2007 Nielsen and Baumgartner[44] showed that root canals irrigated with the EndoVac exhibited significantly less debris 1 mm from the apex than those irrigated with standard syringe and needle technique. In 2010 Shin et al.[46] performed a similar experiment and found significantly less debris remaining 1.5 mm and 3.5 mm from the apices of root canals irrigated with the EndoVac as compared to those irrigated with standard syringe and needle technique. The observed differences in results most likely hinder on the differences in methods utilized for evaluation of root canal cleanliness. In both of the forementioned studies, roots were horizontally sectioned, stained with hematoxylin and eosin, and evaluated under optical microscopy.[44, 46] Horizontal sectioning allows for remaining predentin, tissue, and debris to be stained and quantitatively measured.[30, 343] However, loose debris within the canal lumen may be lost and the root canal system may be contaminated during sectioning.[30]

Variations in methods create difficultly in directly comparing results of previous studies evaluating debridement efficacy of the EndoVac system to those of the current study. Both methods possess inherent weaknesses, and future studies should center on an improved method of root sectioning prior to evaluation. Unfortunately, there are no published studies evaluating the Canal CleanMax and this makes comparison of results

impossible. As previously discussed, future studies should focus on debridement efficacy and safety of the system.

SUMMARY AND CONCLUSIONS

The purpose of this *in-vitro* study was to examine human root canals after hand and rotary instrumentation to determine debridement efficacy when irrigated and aspirated with the EndoVac (Discus Dental, Culver City, CA) versus the Canal CleanMax (Maximum Dental, Inc., Secaucus, NJ). Sixty extracted human canines were instrumented using a combination of hand-instrumentation with Lexicon K-type files and rotary instrumentation with ProTaper files. All canals were irrigated with 6.0-percent sodium hypochlorite and 17-percent ethylenediamine tetra-acetic acid (EDTA). However, the irrigation/aspiration techniques differed among three groups of 20 randomly selected teeth. Group one (control) was irrigated with only a 12-ml Monoject syringe via 30-gauge side-vented, closed-end needle. Group two was irrigated with the EndoVac system. Group three was irrigated similar to group one, but with the adjunct of the Canal CleanMax system. All teeth were sectioned longitudinally, and the sections were divided into coronal, middle, and apical thirds. Each portion of the canal was photographed with a scanning electron microscope (SEM). The photographs were scored by two independent examiners according to relative amount of debris and/or smear layer present, as well as relative number of patent dentinal tubules. These scores were statistically analyzed to determine differences between groups.

Intra-examiner repeatability and inter-examiner agreement of the debris removal scores were assessed using two-way contingency tables, percent agreement, and weighted kappa statistics. If the two examiners disagreed, they reached a 'forced consensus' after

discussing the photograph. Using the consensus scores combined and separately for each of the three locations, the three methods were compared for differences in debris/smear layer removal scores using a Kruskal-Wallis test, which determined if there were any differences among the three groups. If the overall test was significant, Wilcoxon Rank Sum tests were used to compare each pair of groups. Using the consensus scores combined and separately for each of the three irrigation methods, the three locations were compared for differences in debris removal scores using a Kruskal-Wallis test, which determined if there were any differences among the three groups. If the overall test was significant, Wilcoxon Rank Sum tests were used to compare each pair of groups.

The results indicated that the coronal aspect of root canal walls irrigated with the EndoVac system exhibited significantly less debris and smear layer present when compared with the coronal aspect of root canals irrigated with only a standard 12-ml Monoject syringe equipped with 30-gauge ProRinse side-vented, closed-end needle (control). There were no other significant differences in scores between any groups at any location. The EndoVac group exhibited scores suggesting enhanced debridement efficacy over the Canal CleanMax in the coronal and middle thirds, and the control group in the middle third, but the differences were not statistically significant. All aspects of root canals irrigated with the EndoVac and Canal CleanMax resulted in less debris and smear layer present than those irrigated with only a standard 12-ml Monoject syringe equipped with 30-gauge ProRinse side-vented, closed-end needle (control), but these results were not statistically significant. For all locations combined, the EndoVac system produced significantly cleaner root canal walls compared with the control. No significant differences were seen between the Canal CleanMax and the control or Canal

CleanMax and EndoVac. The apical aspect of all root canals in all groups exhibited walls with significantly greater percentages of remaining debris and smear layer compared with coronal and middle thirds.

Based on the conditions of our experiment, negative pressure irrigation delivery with the EndoVac system during and after hand-rotary instrumentation is more effective in removal of debris and smear layer from the coronal third of root canal walls compared with irrigation with a standard 12-ml Monoject syringe equipped with a 30-gauge ProRinse side-vented, closed-end needle. The EndoVac system also provides significantly enhanced debridement efficacy in all combined aspects of the root canal system when compared with irrigation with a standard 12-ml Monoject syringe equipped with a 30-gauge ProRinse side-vented, closed-end needle. The apical aspect of the root canal system exhibited significantly higher portions of the walls inadequately debrided independent of irrigation delivery system. No irrigation delivery method proved superior and all systems proved relatively inadequate in the debridement of the elusive apical third of the root canal system. Cleanliness of this area is arguably most attributable to the success or failure of root canal therapy.

Future studies should implement refined root sectioning techniques to limit incorporation of debris and smear layer into the root canal system. These studies may yield more favorable results in the debridement of the apical one-third of the root canal system. Lastly, the Canal CleanMax should be evaluated further due to the small number of published studies and possible safety concerns associated with its clinical use.

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APPENDIX

APPENDIX I

Two examiners' debris/smear layer scores for anonymously labeled, randomized photographs of middle third of all specimens

Section A					
Specimen	**JB-Score 1**	**JB-Score 2**	**SB-Score 1**	**SB-Score 2**	**Final Score**
1	1	1	1	2	**1**
2	3	3	4	4	**3**
3	2	1	2	1	**2**
4	2	1	2	3	**2**
5	3	3	3	4	**3**
6	1	1	1	1	**1**
7	1	1	1	1	**1**
8	2	2	2	2	**2**
9	1	1	1	1	**1**
10	3	2	4	4	**3**
11	2	2	1	1	**1**
12	1	1	1	1	**1**
13	1	1	1	2	**1**
14	1	1	1	1	**1**
15	1	1	1	1	**1**
16	1	1	1	1	**1**
17	1	1	1	1	**1**
18	1	1	1	1	**1**
19	1	1	1	1	**1**
20	3	3	3	4	**3**

(Continued)

(APPENDIX I cont.)

Section A					
Specimen	**JB-Score 1**	**JB-Score 2**	**SB-Score 1**	**SB-Score 2**	**Final Score**
21	3	3	4	4	**4**
22	1	1	2	3	**1**
23	2	1	2	1	**2**
24	1	1	1	1	**1**
25	2	1	4	4	**3**
26	3	3	3	4	**3**
27	2	1	3	2	**2**
28	1	1	3	2	**1**
29	1	1	2	1	**1**
30	1	1	1	1	**1**
31	3	2	3	4	**3**
32	1	1	1	1	**1**
33	3	3	4	4	**4**
34	1	1	1	1	**1**
35	1	1	1	1	**1**
36	1	1	2	2	**1**
37	2	1	2	3	**2**
38	1	1	1	1	**1**
39	2	1	3	3	**3**
40	4	4	4	4	**4**

(Continued)

(APPENDIX I cont.)

Section A					
Specimen	**JB-Score 1**	**JB-Score 2**	**SB-Score 1**	**SB-Score 2**	**Final Score**
41	1	1	1	1	**1**
42	3	2	2	3	**3**
43	1	1	1	1	**1**
44	3	3	4	4	**4**
45	2	1	1	1	**1**
46	2	1	3	2	**2**
47	1	1	1	1	**1**
48	2	1	3	4	**3**
49	2	1	3	1	**3**
50	2	2	2	2	**2**
51	1	1	1	1	**1**
52	2	1	3	2	**2**
53	3	3	4	4	**4**
54	1	1	1	1	**1**
55	2	1	1	1	**1**
56	3	2	3	3	**3**
57	4	4	4	4	**4**
58	2	1	2	2	**2**
59	2	1	1	2	**1**
60	1	1	1	1	**1**

APPENDIX II

Two examiners' debris/smear layer scores for anonymously labeled, randomized photographs of coronal third of all specimens

Section B					
Specimen	**JB-Score 1**	**JB-Score 2**	**SB-Score 1**	**SB-Score 2**	**Final Score**
1	2	2	3	4	**3**
2	1	1	1	1	**1**
3	1	1	1	1	**1**
4	4	4	4	4	**4**
5	2	2	3	4	**2**
6	3	3	4	4	**3**
7	1	1	2	2	**2**
8	3	3	4	4	**4**
9	3	3	4	4	**4**
10	1	1	1	1	**1**
11	2	1	1	2	**1**
12	2	1	3	1	**1**
13	3	3	4	4	**4**
14	3	2	4	3	**3**
15	2	1	2	2	**2**
16	2	1	2	2	**2**
17	3	3	3	4	**3**
18	1	1	2	1	**1**
19	1	1	2	2	**2**
20	2	1	1	2	**1**

(Continued)

(APPENDIX II cont.)

Section B					
Specimen	**JB-Score 1**	**JB-Score 2**	**SB-Score 1**	**SB-Score 2**	**Final Score**
21	1	1	1	1	**1**
22	1	1	1	2	**1**
23	1	1	1	2	**1**
24	1	1	2	2	**1**
25	1	1	3	2	**2**
26	4	4	4	4	**4**
27	3	3	4	3	**3**
28	3	3	4	4	**4**
29	1	1	1	1	**1**
30	1	1	3	4	**2**
31	2	1	1	2	**1**
32	1	1	1	1	**1**
33	2	2	2	2	**2**
34	1	2	1	2	**1**
35	3	3	4	4	**4**
36	3	2	3	4	**3**
37	1	1	1	1	**1**
38	2	1	4	4	**2**
39	3	3	4	4	**4**
40	1	1	1	1	**1**

(Continued)

(APPENDIX II cont.)

Section B					
Specimen	**JB-Score 1**	**JB-Score 2**	**SB-Score 1**	**SB-Score 2**	**Final Score**
41	1	1	2	2	**2**
42	2	1	3	3	**3**
43	3	2	3	2	**3**
44	1	1	1	1	**1**
45	2	2	3	3	**3**
46	2	1	2	3	**2**
47	1	1	1	1	**1**
48	1	1	1	1	**1**
49	2	2	2	2	**2**
50	2	2	2	2	**2**
51	1	1	1	2	**1**
52	3	3	4	4	**4**
53	3	3	4	4	**4**
54	2	1	3	2	**2**
55	1	1	1	1	**1**
56	1	1	1	1	**1**
57	1	1	1	2	**1**
58	1	1	2	2	**1**
59	1	1	1	1	**1**
60	4	4	4	4	**4**

APPENDIX III

Two examiners' debris/smear layer scores for anonymously labeled, randomized photographs of apical third of all specimens

Section C					
Specimen	**JB-Score 1**	**JB-Score 2**	**SB-Score 1**	**SB-Score 2**	**Final Score**
1	3	3	3	1	**3**
2	2	2	4	2	**2**
3	4	4	4	4	**4**
4	4	4	4	4	**4**
5	1	1	1	3	**1**
6	2	2	2	3	**2**
7	1	1	1	2	**1**
8	3	3	4	4	**4**
9	4	4	4	4	**4**
10	3	3	4	4	**4**
11	2	2	2	3	**2**
12	2	1	2	2	**2**
13	2	2	3	3	**3**
14	4	4	4	4	**4**
15	3	2	2	2	**2**
16	2	1	2	2	**2**
17	3	3	4	4	**4**
18	1	1	1	1	**1**
19	4	4	4	4	**4**
20	1	1	1	1	**1**

(Continued)

(APPENDIX III cont.)

Section C					
Specimen	**JB-Score 1**	**JB-Score 2**	**SB-Score 1**	**SB-Score 2**	**Final Score**
21	1	1	1	1	**1**
22	1	1	1	1	**1**
23	2	2	4	4	**3**
24	3	2	2	3	**2**
25	3	3	4	4	**4**
26	1	1	1	1	**1**
27	2	2	3	3	**3**
28	3	2	4	4	**4**
29	3	3	4	4	**4**
30	3	2	2	4	**3**
31	3	3	4	4	**4**
32	4	3	4	4	**4**
33	4	4	4	4	**4**
34	3	2	3	4	**3**
35	1	1	2	2	**2**
36	1	1	2	2	**2**
37	1	1	1	1	**1**
38	4	4	4	4	**4**
39	3	2	2	3	**2**
40	4	3	2	3	**4**

(Continued)

(APPENDIX III cont.)

Section C					
Specimen	**JB-Score 1**	**JB-Score 2**	**SB-Score 1**	**SB-Score 2**	**Final Score**
41	4	4	4	4	**4**
42	4	4	4	4	**4**
43	2	2	3	3	**3**
44	2	2	2	4	**2**
45	2	1	3	3	**2**
46	2	2	4	4	**4**
47	4	4	4	4	**4**
48	3	2	3	3	**3**
49	4	3	4	3	**4**
50	3	2	3	3	**3**
51	3	3	4	4	**4**
52	3	3	4	4	**4**
53	3	3	3	4	**3**
54	1	1	1	1	**1**
55	2	2	3	4	**3**
56	2	2	2	2	**2**
57	2	2	3	3	**2**
58	1	2	1	2	**1**
59	3	3	4	4	**4**
60	3	4	4	4	**4**

APPENDIX IV

Two examiners' final debris/smear layer scores for Group 1 (control) at each location of all specimens

A		B		C	
Middle		**Coronal**		**Apical**	
Randomized Sample Number	**Final Score**	**Randomized Sample Number**	**Final Score**	**Randomized Sample Number**	**Final Score**
29	1	4	4	11	2
24	1	24	1	7	1
20	3	39	4	8	4
18	1	43	3	6	2
13	1	44	1	58	1
47	1	8	4	42	4
39	3	33	2	29	4
56	3	6	3	25	4
35	1	59	1	3	4
36	1	13	4	36	2
46	2	15	2	24	2
33	4	7	2	23	3
2	3	11	1	33	4
26	3	19	2	59	4
1	1	60	4	17	4
40	4	42	3	4	4
59	1	50	2	5	1
15	1	21	1	15	2
50	2	26	4	45	2
44	4	41	2	38	4

APPENDIX V

Two examiners' final debris/smear layer scores for Group 2 (EndoVac) at each location of all specimens

A		B		C	
Middle		**Coronal**		**Apical**	
Randomized Sample Number	**Final Score**	**Randomized Sample Number**	**Final Score**	**Randomized Sample Number**	**Final Score**
58	2	2	1	34	3
28	1	54	2	57	2
41	1	23	1	53	3
22	1	56	1	31	4
11	1	58	1	2	2
30	1	30	2	9	4
3	2	57	1	30	3
51	1	47	1	13	3
12	1	49	2	47	4
16	1	12	1	10	4
31	3	31	1	1	3
45	1	3	1	18	1
7	1	51	1	54	1
42	3	1	3	26	1
4	2	5	2	14	4
49	3	22	1	28	4
21	4	28	4	19	4
54	1	38	2	55	3
19	1	40	1	51	4
34	1	25	2	37	1

APPENDIX VI

Two examiners' final debris/smear layer scores for Group 3 (Canal CleanMax) at each location of all specimens

A		B		C	
Middle		**Coronal**		**Apical**	
Randomized Sample Number	**Final Score**	**Randomized Sample Number**	**Final Score**	**Randomized Sample Number**	**Final Score**
57	4	9	4	41	4
8	2	55	1	27	3
53	4	32	1	20	1
55	1	20	1	39	2
17	1	35	4	43	3
60	1	52	4	32	4
38	1	45	3	46	4
6	1	48	1	12	2
23	2	29	1	16	2
5	3	18	1	22	1
25	3	34	1	60	4
14	1	10	1	48	3
48	3	16	2	52	4
43	1	17	3	44	2
37	2	46	2	50	3
9	1	53	4	35	2
32	1	27	3	40	4
10	3	36	3	49	4
52	2	14	3	56	2
27	2	37	1	21	1

ABSTRACT

AN *IN-VITRO* SEM STUDY COMPARING THE DEBRIDEMENT EFFICACY OF THE ENDOVAC SYSTEM VERSUS THE CANAL CLEANMAX FOLLOWING HAND-ROTARY INSTRUMENTATION

by

Benjamin P. Ricketts

Indiana University School of Dentistry
Indianapolis, Indiana

This *in-vitro*, prospective, randomized study microscopically compared the debridement efficacy of negative pressure irrigation with the EndoVac (Discus Dental, Culver City, CA) versus the Canal CleanMax (Maximum Dental, Inc., Secaucus, NJ). Sixty extracted human canines were instrumented using a combination of hand-instrumentation with Lexicon K-type files and rotary instrumentation with ProTaper files. All canals were irrigated with 6.0-percent sodium hypochlorite and 17- percent ethylenediaminetetraacetic acid (EDTA). However, the irrigation/aspiration techniques differed among three groups of 20 randomly selected teeth. Group one (control) was irrigated with only a 12-ml Monoject syringe via 30-gauge side-vented, closed-end

needle. Group two was irrigated with the EndoVac system. Group three was irrigated similar to group one, but with the adjunct of the Canal CleanMax system. All teeth were sectioned longitudinally, and the more intact sections were divided into coronal, middle, and apical thirds. Each portion of the canal was photographed with a scanning electron microscope (SEM). The photographs were scored by two independent examiners according to relative amount of debris and/or smear layer present, as well as relative number of patent dentinal tubules. These scores were statistically analyzed using a Krustal-Wallis test and Wilcoxon Rank Sum tests to determine differences between groups. The coronal aspect of root canal walls irrigated with the EndoVac system exhibited significantly less debris and/or smear layer present when compared to the coronal aspect of root canals irrigated with only a standard 12-ml Monoject syringe equipped with 30-gauge ProRinse side-vented, closed-end needle (control). There were no other significant differences in scores between any groups at any location. For all locations combined, the EndoVac system produced significantly cleaner root canal walls as compared to the control. No significant differences were seen between the Canal CleanMax and Control or Canal CleanMax and EndoVac. This study suggested negative pressure irrigation delivery with the EndoVac system during and after hand-rotary instrumentation is more effective in removal of debris and smear layer from the coronal third and combined thirds of root canal walls compared to irrigation with a standard 12-ml Monoject syringe equipped with 30-gauge ProRinse side-vented, closed-end needle.

CURRICULUM VITAE

Benjamin Paul Ricketts

October 10, 1980	Born in Evansville, IN.
August 1999 to May 2010	BS in Biology, Indiana University, Bloomington, IN.
July 2003 to May 2007	DDS, Indiana University School of Dentistry, Indianapolis, IN.
July 2007 to June 2008	Certificate, General Practice Residency, University of Texas Health Science Center, San Antonio, TX.
July 2008 to June 2010	Certificate, Endodontics, Richard Roudebush VA Medical Center, Indianapolis, IN.
July 2010	MSD, Endodontics, Indiana University School of Dentistry, Indianapolis, IN.

Professional Organizations and Licensure

Advanced Cardiac Life Support
American Association of Endodontists
American Board of Endodontics (eligible)
American Dental Association
Academy of General Dentistry
Basic Cardiac Life Support
Colorado Dental Licensure (pending)
Delta Sigma Delta Dental Society
Indiana Dental Association
Indiana Dental Licensure
Northeast Regional Dental Board
Parenteral and Enteral Conscious Sedation